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Award Number: DAMD17-94-J-4068

TITLE: The Effects of a Comprehensive Coping Strategy on Clinical Outcomes in Breast Cancer Bone Marrow Transplant Patients and Primary Caregiver

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REPORT DATE: March 2001

TYPE OF REPORT: Final

PREPARED FOR: U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

DISTRIBUTION STATEMENT: Approved for Public Release;
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20010716 072

REPORT DOCUMENTATION PAGE

Public reporting burden for this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing this collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to Washington Headquarters Services, Directorate for Information Operations and Reports, 1215 Jefferson Davis Highway, Suite 1204, Arlington, VA 22202-4302, and to the Office of Management and Budget, Paperwork Reduction Project (0704-0188), Washington, DC 20503

1. AGENCY USE ONLY (Leave blank)	2. REPORT DATE March 2001	3. REPORT TYPE AND DATES COVERED Final (1 Sep 94 - 28 Feb 01)	

4. TITLE AND SUBTITLE
The Effects of a Comprehensive Coping Strategy on Clinical Outcomes in Breast Cancer Bone Marrow Transplant Patients and Primary Caregiver

5. FUNDING NUMBERS
DAMD17-94-J-4068

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8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING / MONITORING AGENCY NAME(S) AND ADDRESS(ES)

U.S. Army Medical Research and Materiel Command
Fort Detrick, Maryland 21702-5012

10. SPONSORING / MONITORING AGENCY REPORT NUMBER

11. SUPPLEMENTARY NOTES
This report contains colored photos

12a. DISTRIBUTION / AVAILABILITY STATEMENT
Approved for Public Release; Distribution Unlimited

12b. DISTRIBUTION CODE

13. ABSTRACT (Maximum 200 Words)

The major purpose of this 4-year study was to determine the effects of the Comprehensive Coping Strategy Program (CCSP) on pain, fatigue, psychological distress, nausea, health status, burden of care and quality of life in breast cancer patients and their primary caregivers. A randomized controlled clinical trial design was used. 138 patients and 102 primary caregivers participated in the study. Seventy patients were randomly assigned to the CCSP treatment group and 68 to the control group. Data were collected 20 days before hospitalization (baseline), during hospitalization (7 days after the ABMT), and again during the post hospitalization period which was one year following the ABMT. The results showed that breast cancer patients experienced pain, fatigue, nausea and psychological distress prior to, during and post-hospitalization for ABMT. Depression, pain, fatigue and negative coping (catastrophizing) accounted for 41% to 65% of the variance in health status. The CCSP treated group of patients experienced less nausea ($p<.01$), less fatigue and nausea ($p<.05$), were 9% times less likely to die ($p=.05$), and had a higher quality of life ($p<.05$ to $p<.01$) than patients in the control group. The patients' primary caregivers at baseline suffered from moderate anxiety. Anxiety and fatigue were more severe in female PCGs and those who were single ($p<0.05$ to $p<0.01$). Family, a subscale of quality of life, was predictive of objective burden of care ($p<0.05$). Age and trait anxiety were significant predictors of subjective burden of care ($p<.05$). The mean total quality of life score was higher in the treatment group (M=43.61) at 1 year follow-up than in the Control group (M=21.52). Quality of life was lower in the control group at follow-up than at baseline, whereas in the treatment group we found the opposite. At 2 years follow-up, 21 subjects in the treatment group and 21 subjects in the control group had died.

14. SUBJECT TERMS
Breast Cancer, Pain, Anxiety, Depression, Fatigue, ABMT, Primary Care Giver, Coping

15. NUMBER OF PAGES
139

16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT Unclassified	18. SECURITY CLASSIFICATION OF THIS PAGE Unclassified	19. SECURITY CLASSIFICATION OF ABSTRACT Unclassified	20. LIMITATION OF ABSTRACT Unlimited

NSN 7540-01-280-5500

FOREWORD

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Fannie Gaston-Johansson   04/05/01
PI - Signature   Date

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(1) INTRODUCTION

Autologous bone marrow transplantation (ABMT) consists of the administration of high-dose chemotherapy and in some cases, total body radiation, followed by rescue with autologous, cryopreserved, bone marrow cells. This treatment regimen has become an established alternative treatment in a variety of malignant diseases including breast cancer[1]. While potentially life saving, ABMT can be a traumatic procedure and can seriously impact the patient's quality of life (QOL). The often severe and unrelenting pain from the treatment regimen, medical procedures and persistent adverse physical side effects such as pain, fatigue and nausea and vomiting result in a critically ill and psychologically distressed patient. These symptoms in turn affect the patient's health status and QOL[2-3]. The patient's primary caregiver may also experience psychological distress, severe fatigue, increased burden of care, and a less than optimum QOL[4-9].

The overall purpose of this study was to measure the effects of a comprehensive coping strategy program (CCSP) (Appendix 1) on pain, psychological distress, fatigue, perceived health status, burden of care, and QOL for breast cancer ABMT patients and their primary caregivers.

(2) BODY

A.   ABMT Patients

Pain associated with ABMT is well documented and is related to either the conditioning regimen and/or the ABMT procedure itself. Painful side effects of ABMT include the following: gastrointestinal complications- painful effects on the epithelial membranes of the oral cavity (stomatitis and ulcerations); gastritis, diarrhea and nausea and vomiting; genitourinary complications- painful effects on the mucosal epithelial membranes of the bladder wall (chemical cystitis), renal complications; veno-occlusive disease; pancytopenia effects- infection, high fever, sepsis, hemorrhage; neurological complications; cardiac toxicities; alopecia with resultant effects on body image; and fatigue[2, 3, 10]. ABMT treatment causes pain through necessary invasive procedures such as bone marrow aspirations, spinal taps and Hickman Catheter placement. Rappaport[11] reported that anxiety and depression were the most common psychological reactions in patients post-ABMT. The subtle and overt interrelationships among the many potential physical and psychological symptoms related to ABMT make care of this population a very complex process.

As ABMT therapeutic advances for breast cancer have led to improvement in prognosis and overall survival, emphasis on the psychosocial well-being of the patient has become more important[12]. Anxiety regarding painful procedures, strict protective isolation, and depression were universal reactions during and for several months following ABMT[13]. Gaston-Johansson and associates[5] found that ABMT patients had moderate anxiety and depression during hospitalization and at discharge with anxiety and depression reaching peak intensity 5 days post ABMT. Jenkins and associates[14] found that 40% of ABMT patients, suffered from major depression at some stage during the transplant procedure. Case studies and anecdotal description suggest that strict protective isolation, medical procedures, and pain are frequent contributors to anxiety and depression in ABMT patients, with pain described as the most frequent factor[14]. Research documenting a positive relationship of pain to anxiety and depression in cancer patients is extensive[15, 16].

About 33-76% of patients who undergo ABMT experience a high degree of fatigue[17]. Frequency and severity of pain, psychological distress and fatigue influences a patient's perceived health status, QOL and length of hospital stay[18]. Additional research targeting treatment-related fatigue and patient response to this symptom is needed[19].

Coping strategies of breast cancer patients have been recognized as a critical component of psychosocial well-being. Some of the psychological aspects of the BMT process are well known: decreased contact with supportive persons because of protective isolation; anxiety related to the unpredictability of the progress through the BMT experience; and side effects[20]. Numerous factors affect psychosocial reactions to the BMT experience: age; social support; personality/intelligence; financial worries; religion; culture; and past experiences[21]. However, few longitudinal studies conducted over time to explore these factors have been completed[22]. Although few studies have been conducted to identify psychosocial aspects of the BMT experience from the patient's perspective, a hermeneutical inquiry was conducted which identified five major themes of coping patterns among BMT patients: physiological functioning; alertness; attitude; social relationships and; spirituality[20].

A patient's beliefs about his/her health status have been shown to be an important determinant of health outcomes[9]. The health status of ABMT patients varies. Some breast cancer ABMT patients leave the hospital within three weeks, while others stay 2 to 3 months. About 35% of patients utilize emergency room services and about 15 to 50% require one or more rehospitalizations[23].

B.   Primary Caregiver (PCG)
It is well recognized that cancer impacts not only the patient, but also persons who comprise the patient's support system[24, 25, 26, 27, 28]. Northouse[28] presented summary empirical evidence from 19 studies that families may experience similar emotions as the breast cancer patient. The PCG is the person identified by the patient as the significant other. The PCG is usually the single greatest support person for the patient during the transplant process and at other difficult times[29]. Not only does the PCG devote energies to the patient during the pretransplant period and peritransplant period, but also because of the decreased length of stay for the ABMT patient additional responsibilities may be added: dispensing oral medications and administering intravenous fluids and medications via an infusion pump; and assessment of the patient in the home for sequel of the ABMT process- fever, nausea and vomiting, diarrhea or other reportable side effects and symptomatology[30]. Few studies to date have documented the PCGs psychological distress or negative outcomes related to care of the breast cancer ABMT patients, or how they cope with problems related to caregiving burden. Pistrang and Barker[26] explored the role of the helping relationship with the partner related to women's psychological response to breast cancer. Their findings suggest that the partner plays a key role in breast cancer patients' adaptation and also that interventions focusing on couples may be effective in reducing psychological distress [26]. Burdens which can contribute to this distress include the patient's medical regimen, the constant/multiple patient demands prior to, during and months/years after ABMT, possibly traveling long distances and displacement from home, friends and work, possibly living with a very ill person for a long time, and competing family/work responsibilities. There is some evidence that caregivers experience positive reactions[29]. However, most investigators suggest that caregivers responsibilities have negative effects on the caregivers' QOL[6]. Caregivers frequently demonstrate poor health and severe fatigue, in addition to frustration, anxiety and depression. Improving support within this close relationship may lessen PCG burden of care and allow for better adjustment to the cancer experience for both the patient and the PCG.

C.   Comprehensive Coping Strategy Program (CCSP) (Appendix 1)
The Gate-Control Theory of pain by Melzack and Wall[15] and the Stress, Coping and Adaptation Paradigm by Lazarus[16] provide the theoretical framework for this study. Pain is defined as a multi-dimensional sensory and affective experience associated with discomfort[15]. Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and /or internal demands that are appraised as taxing or exceeding the resources of a person[16]. Positive coping strategies refer to internal thoughts and behaviors people use to manage their pain, or their emotional

reactions to the pain and to reduce emotional distress. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future[23, 31].

Previous research studies have shown that pain and emotional distress can be reduced in pain patients by providing a comprehensive coping strategy program (CCSP) which includes: preparatory information to increase control[31]; b) cognitive restructuring which includes positive coping statements and avoidance of catastrophizing[31]; and c) relaxation with guided imagery. A combination of these three components has been found to be the best overall coping intervention to reduce pain and stress rather than using each component separately[31]. However, no prospective or retrospective study was found in the scientific literature which included these three components in a unified coping strategy program to reduce pain and emotional distress and fatigue in breast cancer ABMT patients.

(3) HYPOTHESES

Hypotheses examined were:

A.   Breast cancer patients who receive ABMT and participate in a CCSP will demonstrate greater improvements over time in pain, psychological distress, fatigue, perceived health status, and quality of life than breast cancer ABMT patients who do not receive the CCSP.

B.   Primary caregivers, of breast cancer patients who receive ABMT and participate in a CCSP, will demonstrate greater improvement over time in burden of care, psychological distress, fatigue, and quality of life than primary caregivers of ABMT patients who do not receive the CCSP.

(4) RESEARCH OBJECTIVES

A.   Research objectives Hypothesis A:

1.   To describe pain, psychological distress, and health status in breast cancer patients during the pre-hospitalization for ABMT time period.
2.   To examine the relationships among pain, psychological distress, catastrophizing, coping, and perceived health status in breast cancer patients during the pre-hospitalization for ABMT time period.
3.   To describe the percentage of variance within the concept of health status, which was explained by, pain, psychological distress, and coping.
4.   To describe the prevalence and severity of fatigue, pain, depression, and alterations in health status in breast cancer patients with metastatic disease.
5.   To determine if fatigue, pain, and depression and catastrophizing are significant predictors of health status.
6.   To determine if a significant difference existed in the pain, fatigue, psychological distress, and nausea between patients with breast cancer who receive ABMT and the CCSP and patients with breast cancer who receive ABMT but do not receive the CCSP.
7.   To determine if a Comprehensive Coping Strategy Program has an effect on mortality and survival in breast cancer patients treated with ABMT.
8.   To determine if patients with breast cancer find a comprehensive coping strategy program beneficial.
9.   To determine the effects of a comprehensive coping strategy program on quality of life in patients with breast cancer who have undergone an ABMT.

B. Research Objectives related to Hypothesis B

1. To describe the prevalence and severity of psychological distress, fatigue, burden of care and quality of life in primary caregivers of patients who have been treated for breast cancer and are scheduled for ABMT.
2. To examine the relationships among QOL, depression, anxiety, fatigue and burden of care.
3. To determine if anxiety, depression, fatigue and QOL are significant predictors of burden of care.
4. To determine the if there is a significant difference between the CCSP treated group and the control group with regard to psychological distress, fatigue, burden of care and QOL in primary caregivers of patients who undergo bone marrow transplant for breast cancer.

(5) METHODS AND INSTRUMENTATION

A. Study Design
The study has a prospective randomized controlled clinical trial design with repeated treatment and measurements. Participants were randomized to one of two comparison groups for the purpose of measuring the effect of the proposed intervention, i.e. participation in the CCSP. Group I was composed of breast cancer patients and their PCGs who received the CCSP intervention. Group II included breast cancer patients and their PCGs who did not receive the CCSP. Eligibility criteria for participation in the project were as follows: 1) scheduled to receive ABMT for stage II, III or IV breast cancer; 2) able to speak and read English; 3) age> 18; 4) able to give informed consent.

B. Subjects: Participation Rate and Follow-up of Patients
The number of patients who entered the study was 142 of which 4 declined participation (Figure 1). (Appendix 2) The subjects were recruited to the study over a period of 3 1/2 years.

1. Baseline
At baseline, data were collected on 138 subjects. Following the collection of baseline data, 68 subjects are randomly assigned to a control group and 70 to the CCSP treatment group.

2. During Hospitalization
Of the 138 subjects on which baseline data were collected, only 110 subjects remained in the study when data were collected 2 days before and 7 days after the bone marrow transplant. Fifty-eight were in the control group and 52 in the CCSP treatment group. The number of subjects decreased because 10 were too ill to complete questionnaires (questionnaires used in study can be found in Appendix 10), 8 had their ABMT canceled, 3 died and 7 withdrew from the study (Figure 1) (Appendix2).

3. Post-Hospitalization Follow-up - ≥ to 12 Months
Of the 110 subjects on whom data were collected during hospitalization, data were collected during post-hospitalization on 70 plus an additional 3 subjects who had completed baseline data, but were too ill to participate during hospitalization. Thirty-five subjects were in the control group and 38 in the CCSP treatment group. The number of subjects decreased because 13 of the 110 subjects died prior to follow-up, and 27 had not at the time of this report reached the time required for follow-up (Figure 1) (Appendix 2).

C. Subjects: Participation Rate and Follow-up of PCGs

The number of PCGs who participated in the study at baseline were 102 of which 55 were in the CCSP

treated group and 47 PCGs in the control group. There were 72 PCGs remaining in the study during the patients hospitalization. There were 35 PCGs (18 in the control group and 17 in the treatment group) remaining in the study ≥ 12 months after the patients' ABMT. Major reasons for dropout were separation from the patient, inability to locate PCGs, death of patients, and PCG refusal to continue the study.

D.   Patient Variables and Instruments

1.   Sociodemographic and Background Variables
The information about demographic and background variables was collected on a standardized form and included the following information: age; gender; race/ethnicity; marital status; educational level; religion; household income; employment status; occupation; and whether the subjects lived alone or with another person.

2.   Pain Intensity and Quality
The Painometer (POM) is a hard white plastic tool that measures 8 inches long, 2 inches wide and 1 inch thick. It is light weighted and can easily be held by the subject. A list of 15 sensory and 11 affective pain descriptors are located on the front side of the POM and a 100 mm visual analogue scale with a moveable marker is located on the back side of the POM (POM-VAS). An intensity value (from a low of one to a high of five) is pre-determined for each sensory and affective word located on front of the POM. A maximum score can be obtained for the sensory component of pain and for the affective component. A total score can be obtained by adding the sensory and affective scores. Test-retest reliability of the POM has been demonstrated as well as criterion related[34] and construct validity[32-36].

3.   Psychological Distress
Anxiety and depression were assessed as measures of psychological distress. Anxiety was measured using the State-Trait Anxiety Inventory (STAI). The STAI consists of two separate self-report scales for measuring state and trait anxiety[37]. State anxiety is a transitory emotional response to a stressful situation. Trait anxiety reflects a stable predisposition to anxiety as determined by a personality pattern. Respondents rate themselves in relationship to the statement on a Likert scale from 1 to 4. The total score is the sum of all 20 responses and ranges from a minimum score of 20-39 (low anxiety), 40-59 (moderate anxiety), to a maximum score of 60-80 (high anxiety). Test-retest reliability and validity have been demonstrated for the STAI[37]. Depression was measured using the Beck Depression Inventory (BDI). The BDI consists of 21 items that describe particular symptoms of depression[38]. Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores ranging from 0 to 9 are normal, 10 to 15 mild depression, 16 to 23 moderate depression, and 24 to 63 severe depression. The total score (range 0 to 63) is obtained by summing the 21 responses. Test-retest correlations of the BDI ranged from .60 to .90 in nonpsychiatric patients[38].

4.   Fatigue and Nausea
The Piper Fatigue Scale (PFS) was used to measure fatigue. This scale was designed to measure fatigue as a multidimensional phenomenon, defined as "a subjective feeling of tiredness, influenced by circadian rhythm, and other factors varying in duration, unpleasantness, and intensity"[39]. The scale consists of 41 horizontal 100 mm VAS items measuring four dimensions of subjective fatigue: 1) temporal dimension; 2) intensity/severity dimension; 3) affective dimension; and 4) sensory dimension. A total fatigue score is calculated by summing the four scores and dividing by four[39] . A 100mm visual analogue scale was also used to measure overall fatigue and nausea.

5. Perceived Health Status

The Short-Form Health Survey (MOS-FS)[40] was used to measure perceived health status. The 20-item survey assesses physical functioning (6 items), role functioning (2 items), social functioning (1 item), mental health (5 items), health perception (5 items) and pain (1 item)[40]. Reliability[40] and construct validity has been demonstrated for the MOS-SF.

6. Coping Strategies

The Coping Strategy Questionnaire (CSQ), developed by Keefe[23], was used to assess a person's use of pain coping strategies. The categories of coping strategies assessed by this measure include:1) diverting attention; 2) reinterpreting pain sensations; 3) ignoring pain sensations; 4) praying and hoping; 5) catastrophizing; and 6) increasing activity level. For each category of coping strategies there are 6 items on the CSQ with scores ranging from 0 to 36. Each item is rated on a 7 point scale to indicate how often that strategy is used to cope with pain (0 = never, 3 = sometimes, and 6 = always). The CSQ also includes 2 items which measure overall effectiveness of those strategies used by asking the subjects to rate on a 7-point scale (with scores ranging from 0 to 6) how much control they have over the pain, and how much they are able to decrease their pain23. Reliability and construct validity have been demonstrated for the CSQ[23].

7. Burden of Care

Burden of care (BOC) was assessed using the Measurement of Objective Burden (MOB) and the Measurement of Subjective Burden (MSB) scales developed by Montgomery, Gonyea and Hooyman41. The MOB is a 9-item, 5-point scale ranging from (1), " a lot more or better", to (5), "a lot less or worse", designed to assess the extent to which caregiving behaviors have changed the caregiver's lives in nine areas: time for oneself; privacy; money; personal freedom; energy; recreational/social activities; vocational activities; relationships with other family members; and health. The MSB is a 13-item, 5-point scale from (1) "rarely or never" to (5) "most of the time", designed to assess attitudes toward or emotional reactions to the caregiving experience. Items for the MSB were adapted from the 29-item inventory relating to attitudes and feelings about caregiving developed by Zarit and associates[42]. Reported alpha was .85 for the MOB scale and .86 for the MSB scale[41].

8. Quality of Life

QOL was measured by the Quality of Life Index (QLI), which consisted of 35 items that are categorized into the following subscales[43]: health and functioning, socioeconomic, psychological/spiritual, and family. The tool uses 6-point ordinal scales to measure both the satisfaction with and the importance placed on each item by the individual. Responses range from 1 (very dissatisfied/unimportant) to 6 (very satisfied/important). Final scores ranged from 0 to 30, with higher scores indicating greater QOL[43].

Reliability and validity of the QLI were established in a number of studies by Ferrans[43]. Concurrent validity was supported by a strong correlation (r = 0.80) between the QLI and a question evaluating overall satisfaction with life. Alpa reliability for the total score was 0.95. Internal consistency was reported for the subscales on the QLI at 0.90 for health and functioning, 0.84 for socioeconomic, 0.93 for psychological/spiritual, and 0.66 for family[43].

E. CCSP Intervention

Purposes

The three purposes of the CCSP are to: 1) teach the patient and PCG how to decrease and control pain and discomfort; 2) enhance the coping ability of the patient and PCG by teaching them to recognize distorted thinking, and how to use positive coping self-statements and; 3) teach the patient and PCG how to use relaxation with imagery. The goal of the CCSP is to reduce pain, psychological distress, and reduce fatigue that is known to be intensified by pain and psychological distress. A decrease in these symptoms is expected to positively influence the subjects perceived health status and QOL. A detailed description of the CCSP is presented in the Appendix 1.

F. Data Collection Procedure, Statistical Analysis and Results

Data collecting procedures, statistical analysis and results specific to each patient objective 1 - 7 are presented in Papers I - IV (See Appendix 3-6). Objectives 8 and 9 are presented in paper 5 (Appendix 7).

G. General Statistical Analysis

For each time periods of data collection: baseline, during hospitalization and post hospitalization, exploratory data analysis examining distribution, outliers and missing data were routinely performed prior to any bivariate association testing. No imputation or extrapolation was made for values, which were missing or fell out of range. Number of subjects under these categories was extremely small however, and thus did not influence final results. The scores for all physiological (pain, fatigue) psychological(anxiety, depression, coping), QOL, health status domains were computed using the weighted number of items answered for a particular sub-scale by the respondent. However, the subject was omitted from that sub-scale if she had less than 50% of the items in a particular sub-scale reported. Additionally, the direction of the sub-scale scores were also reviewed in relation to standard range and direction of the score reported in the original instrument. Subsequent correlation coefficients, means and standard deviations, and independent association of proportions were obtained and compared between the treatment and control groups, to evaluate the significance of the association at cross-sectional and longitudinal levels. Finally, to test hypothesis originally proposed, multiple linear and logistic regressions were performed to determine the treatment effectiveness, when co-variates were taken into account.

(6) RESULTS

A. A summary of findings related to Objectives 1-7 are presented below (Appendix 3-6)

Gaston-Johansson, F., Fall-Dickson, J., Bakos, A.B., Kennedy, M.J. (1999). Fatigue, Pain, Depression in Pre-Autotransplant Breast Cancer Patients. Cancer Practice. Sept/Oct. Vol. 7, No. 5: pg. 240-7.

In this paper our research team characterized multiple symptoms (fatigue, pain, depression) experienced by women with breast cancer who were treated with mastectomy and chemotherapy prior to autotransplantation. We also showed that pain and depression accounted for 60% of the variance in total health status, and that fatigue and depression accounted for 41% of the variance in the patients perception of her health status. A patient's beliefs about his/her health status have been shown to be an

important determinant of health outcomes (Appendix 3).

Gaston-Johansson, F., Ohly, K., Fall-Dickson, J., Nanda, J., Kennedy, M.J. (1999). Pain, Psychological Distress, Health Status, and Coping in Patients with Breast Cancer Scheduled for Autotransplantation. Oncology Nursing Forum. Vol. 26, No. 8., pg. 1337-45.

In this paper, our research team was able to characterize pain, psychological distress, health status and coping experienced by women with breast cancer who were treated with mastectomy and chemotherapy prior to autotransplant. We found that 24% of the patients suffered moderate anxiety and 26% suffered from severe/high anxiety. Moderate depression was experienced by 17% and severe/high depression was reported by 7% of the subjects. The subjects reported a mean total health status score of 50.30 (SD = 10.67, range 18 to 72) out of a possible score ranging from 0 to 91. There were strong correlations between depression and total health status (-.73,$p<0.001$). We also found that sensory pain, depression and catastrophizing (a negative coping strategy) accounted for 65% of the variance in health status (Appendix 4).

Gaston-Johansson, F., Fall-Dickson, J., Nanda, J., Ohly, K., Stillman, S., Rogers, L., Kennedy, M.J. (2000) The Effectiveness of the Comprehensive Coping Strategy Program on Clinic Outcomes in Breast Cancer Autologous Bone Marrow Transplantation Patients. Cancer Nursing. Vol. 23, No. 3.

Major findings from our research are presented below.

In the CCSP group, nausea was more severe on day -2 than on day +7. The opposite was the case in the control group with nausea reaching its greatest intensity level on day +7. On day +7 nausea was 23 points higher in the control group compared to the CCSP group. **There was a statistically significant difference between the groups regarding nausea on day +7 with the CCSP treatment group reporting less nausea than the control group F $(1, 72)$ = 5.50, $p<0.05$). After controlling for demographic variables and the nausea score on day -2, there was still a group difference on day +7 with the CCSP group showing statistically significant lower scores than the control group (B=-16.94, Beta=-.28, $p<0.05$).** Nausea is a major problem for patients receiving chemotherapy and autotransplantation. The CCSP appears to be an effective treatment strategy against nausea.

Fatigue reached peak levels on day -2 for both groups with fatigue increasing by 10.80 points in the CCSP group from baseline to day -2 compared to 20.33 points in the control group. On day +7, the control group rated fatigue as 9.44 points higher than the CCSP group. There were no statistically significant differences in fatigue levels between the groups on day -2. On day +7, after controlling for fatigue on day -2, there was a significant difference between the groups F $(1, 63,)$ = 4.01, $p<0.05$. However, after controlling for demographic variables and fatigue on day -2, there were no statistically significant differences between the groups. **When an index of nausea + fatigue was created for day +7, and after controlling for demographic variables, there was a significant difference between the groups with the control group having higher scores B= -26.23, Beta-.27, $p<0.05$.** Fatigue is a major problem for breast cancer patients who receive chemotherapy and autotransplantation (Appendix 5).

Gaston-Johansson, F., Nanda, J., Kennedy, J. (1999) The Effect of a Comprehensive Coping Strategy Program on Mortality, (submitted to Journal of American Medicine Association) examines the effect of the CCSP on mortality and survival. A total of 16 patients (14.5%) had died when follow up was carried out. When stratified by group, 4 patients in the CCSP group (7.7%), compared to 12 in the control group[(20.7%) had died at follow up. **There were statistically**

significantly fewer deaths in the CCSP treated group than the control group (p<0.5). The mean survival period was 341 days for the CCSP group compared to 233 days for the control group at follow-up. The odds ratio for mortality among the CCSP group was 0.32 (p<0.05) (Table I). Breast cancer patients in the CCSP treated group were 9% (1.7-41.6), p<0.001, less likely to die than the breast cancer patients in the control group (Appendix 6).

Discussion of findings related to objectives 1-7
The patients who underwent bone marrow transplantation experienced multiple distressing symptoms that were significantly reduced with a CCSP combined with usual treatment. Nausea, and nausea combined with fatigue were statistically reduced in a group of breast cancer patients treated with a CCSP compared with a non-treated control group.

As hypothesized, patients with breast cancer who underwent bone marrow transplant and received the CCSP, where less likely to die than the comparison group (7.7% Vs 20.7%). This difference was both clinically and statistically significant. These results appear to indicate that the CCSP treatment may have been effective. It appears from our study, that the probability of survival did not diverge until about one year following ABMT. The demographic characteristics of the sample did not influence the findings related to mortality, nor did the stage of the disease or the type of chemotherapy.

The results of survival between groups need to be interpreted with caution. All patients have not been in the study for the same length of time regardless of group assignment. The mean survival time, which was 341 days for the CCSP group and 233 days for the control group (table I) could be a function of the patients' length of time in the study. For this reason we introduced follow up since ABMT as a covariate. Entry of this variable into the final model reduced the mortality likelihood for the CCSP group from 15% to 11% and lowering the p value from 0.06 to 0.05. It is possible to obtain statistically significant differences between groups in mortality once the participants have been in the study for a longer period of time than the current follow up period.

The emphasis of the CCSP was to help patients cope with multiple symptoms and stress while improving their quality of life and survival. At no time did our research team intend for the CCSP to influence the course of the disease or the mortality of the patients. A theoretical discussion is presented in the manuscript listed below along with tables and figures in an attempt to explain our results.

B.   Results related to Objective 8

Gaston-Johansson, F., Lachica, E., Nanda, J. Kennedy, J (1999) The Effects of a Comprehensive Coping Strategy Program on Quality of Life and Mortality (Abstract submitted for presentation at the International Cancer Nursing Conference) (Appendix 9)

This presentation deals with the patient's evaluation of the CCSP. A summary of the findings is presented below.

Benefits Effectiveness of the CCSP Intervention from the Patients Perspective

The CCSP intervention (handouts and audiotapes) was reinforced according to protocol in all subjects who remained in the study. In addition, patients were instructed to use the CCSP at least once a day during hospitalization on a routine basis. The patients in the treatment group were also instructed to identify other situations in which they felt that the CCSP intervention was helpful and to record in the

diary the situation in which the CCSP handouts and audiotapes were used. The patients were also instructed to document whether or not the CCSP intervention was beneficial in relieving their symptoms.

It was interesting to note the time of day and the situations in which the patient chose to use the CCSP handouts and audiotapes. The most frequent use of the CCSP intervention was during the evenings around bedtime. The most frequent symptoms/problems for which the patients used the CCSP intervention were psychological problems (51%) and sleep problems (60%). Twenty one percent of the patients used the CCSP to deal with chemotherapy side effects. The CCSP handouts and audiotapes were used 385 times by the patients. Both the handouts and the audiotapes were beneficial based on the patients reports. However, the patients documented the CCSP audiotapes as more beneficial. The audiotapes were used over 50% more often than the handouts. Twenty one (78%) of the patients reported that the audiotapes were effective 90-100% of the time compared to 19 (70%) of the patients reporting that the handouts were beneficial 90 to 100% of the time. Four (15%) of the subjects found the handouts to be beneficial 50 - 89 % of the time compared to 6 (22%) of the subjects reporting the audiotape to be beneficial 50 - 89 % of the time. Four patients reported that the handouts were beneficial less than 50% of the time. The remaining subjects in the treatment group only indicated that they had used the CCSP according to protocol and did not record additional situations in which they had used the handouts and audiotapes.

Discussion of Findings

The patients overwhelmingly reported that they found the CCSP intervention helpful. They used the CCSP intervention during critical points in their treatment and on days when they experienced most side effects from the ABMT and found the CCSP intervention to be helpful 90 to 100% of the time. The subjects used the CCSP in situations that are supported theoretically in the scientific literature for use of behavioral treatment strategies such as to decrease their psychological distress, to decrease side effects of chemotherapy, and to induce sleep. Although the CCSP was mainly used during the evenings, it was also frequently used during the afternoons.

The patients used the CCSP audio-tapes more frequently and found them to be more helpful than the CCSP handouts. The increased use of the audio-tapes may be explained by the fact that it is a procedure that has to be followed whereas the handouts support cognitive restructuring. Hopefully, the information in the handouts gradually becomes an automatic part of the subjects' thinking processes, and therefore do not need to be read so frequently. The audio-tapes make relaxation possible through the participation of subjects in a carefully outlined progressive relaxation procedure combined with imagery. The audio-tapes are also designed to help the subjects become relaxed more quickly as they become more comfortable with the information and instructions on the tape.

The benefits derived from the CCSP, as experienced by the patients, have important implications for clinical practice. The effects of the CCSP may be helpful to a broader group of cancer patients who are treated with chemotherapy for breast cancer but do not receive the ABMT. The audio-tape is inexpensive and can easily be used in a variety of situations to help cancer patients cope with psychological distress, and sleeplessness. Clearly, the breast cancer patients in the treatment group in this study have overwhelmingly acknowledged the benefits of the CCSP.

C. Results Related to Objective 9

Gaston-Johansson, F. Ohly, K., Nanda, J., Lachica, E., Kennedy. J. The Impact of the CCSP on Quality of Life of Breast Cancer Autologous Bone Marrow Transplantation Patients

In this study, we tested the effectiveness of CCSP on the 12-month follow-up QOL measures. The CCSP treated group had a statistically significantly higher overall quality of life (p<.05), psychological well-being, socioeconomic well-being (p<.05), and spiritual wellbeing (p<.01) than the control group at follow-up. As expected, there were significant correlations among the overall QOL and subscales of QOL. With the exception of a significant correlation between state anxiety and socioeconomic and family well-being, all other QOL scales were statistically significantly correlated to state and trait anxiety and depression. There were no significant correlations between health locus of control variables and overall QOL and the subscales of QOL. Coping self-statements, reinterpretation and avoidance of catastrophe were significantly related to different QOL scales (Appendix 7)

Effectiveness of the CCSP
A model measuring the effectiveness of the CCSP on Quality of Life (total and subscale scores) constructs at follow-up a year or more after autotransplant among patients with breast cancer is presented in Table 5. The CCSP treated group showed significant improvement in overall QOL (Beta=0.31, p<.01), psychological well-being (Beta=0.24, p<.05), social wellbeing (Betas=0.25, p<.05), and spiritual wellbeing (Beta=0.36, p<.01) than the control group without any adjustment factor. With incremental adjustment for baseline QOL, disease stage, chemotherapy type, demographics, trait anxiety, coping self-statements and avoidance of catastrophe, and internal/powerful others locus of control and depression (Table 5). The results showed that the CCSP improved the QOL (Beta=0.26, p<.05; R^2= 49%), psychological well-being (Beta=0.28, p<.05; R^2 =51%) and spiritual well-being (Beta=0.39, p<.05; R^2=39%) of breast cancer patients at one year follow-up and more after an autotransplant (Appendix 7).

D. Results Related to Primary Caregivers: Objectives 1 - 4

Gaston-Johansson, F., Psychological Distress, Fatigue, Burden of Care, and Quality of Life in Primary Caregivers (PCGs) of Breast Cancer ABMT Patients

One hundred and two PCGs participated in the study (55 in the CCSP treated group and 47 in the control group). The majority of the PCGs for breast cancer patients were male, white, married, college graduates, and Protestants. They had incomes above $50,000, were professionals and worked full time.

The PCGs reported a low-grade level of fatigue, moderate anxiety and a relative high level of burden of care. Depression was not a problem for the subjects. On the other hand, anxiety and fatigue were more severe in females and PCGs who were single (p<0.05 to p<0.01).

Quality of life as measured by each of the subscales was low. All variables were significantly correlated to each other except for subjective burden and temporal and sensory fatigue.
There was no significant predictor (anxiety, depression, fatigue and quality of life) of objective burden of care. Age (Beta = -.242, B = -.122, t = -2.20, p<.05) and anxiety Beta = -.345, B = -.224, t = 2.02, p<.05) were significant predictors of subjective burden (Appendix 8).

(7) KEY RESEARCH ACCOMPLISHMENTS:

- Breast cancer patients who underwent ABMT experienced multiple symptoms that affected their health status and quality of life.
- A comprehensive Coping Strategy Program (CCSP) was effective in reducing multiple symptoms, and improving the quality of life of breast cancer patients who were treated with ABMT.
- Breast cancer patients who received the CCSP lived significantly longer than breast cancer patients who did not receive the CCSP
- Primary Caregivers of breast cancer patients who received the CCSP had a significantly lower subjective burden of care than a control group.
- Breast cancer patients who received the CCSP reported significantly greater quality of life than breast cancer patients who did not receive the CCSP.

(8) REPORTABLE OUTCOMES (Appendix 9)

Articles and Manuscripts
*Peer reviewed
**Competitively selected
† Data-based article

Foxall, M, Gaston-Johansson, F. "Quality of life of family caregivers of hospitalized bone marrow transplant patients." Submitted for publication to the Journal of Advanced Nursing.

Gaston-Johansson, F., Fall-Dickson, J., Nanda, J., Ohly, K., Stillman, S., Rogers, L., Kennedy, M.J. (2000) The Effectiveness of the Comprehensive Coping Strategy Program on Clinical Outcomes in Breast Cancer Autologous Bone Marrow Transplantation Patients. Cancer Nursing. Vol. 23, No. 3.

Gaston-Johansson, F., A description of psychological distress, fatigue, burden of care and quality of life in primary care givers (PCGs) of breast cancer patients scheduled for ABMT. (Submitted)

Fall-Dickson, J. M. & Gaston-Johansson, F. (2001). Pain in the breast cancer patient: Assessment and role of the oncology nurse. Breast Cancer Online, Vol 4, March.

Gaston-Johansson, F., Fall-Dickson, J., Nanda, J., Ohly, K., Stillman, S., Rogers, L., Kennedy, M.J. (2000) The Effectiveness of the Comprehensive Coping Strategy Program on Clinic Outcomes in Breast Cancer Autologous Bone Marrow Transplantation Patients. Cancer Nursing; Vol. 23, No. 3.*†

Gaston-Johansson, F., Ohly, K., Fall-Dickson, J., Nanda, J., Kennedy, M.J. (1999). Pain, Psychological Distress, Health Status, and Coping in Patients with Breast Cancer Scheduled for Autotransplantation. Oncology Nursing Forum. Vol. 26, No. 8., pg. 1337-45. *†

Gaston-Johansson, F., Fall-Dickson, J., Bakos, A.B., Kennedy, M.J. (1999). Fatigue, Pain, Depression in Pre-Autotransplant Breast Cancer Patients. Cancer Practice. Sept/Oct. Vol. 7, No. 5: pg. 240-7. *†

Presentations
Gaston-Johansson, F. (2000). "The Effects of a Coping Strategy Program on Quality of Life and Mortality." Poster Presentation – 11th International Conference on Cancer Nursing, July 30 – August 3: Oslo, Norway.**

Gaston-Johansson, F. (2000). "The Effects of a Coping Strategy Program on Quality of Life and Mortality." Poster Presentation – *Era of Hope* Department of Defense Breast Cancer Research Program Meeting, June 8-12: Atlanta, Georgia.**

Gaston-Johansson, F. (1999). "Fatigue, Pain, and Depression as Predictors of Health Status in Breast Cancer Patients." Poster Presentation – Seeking Excellence in Nursing sponsored by The Institute for Johns Hopkins Nursing and Johns Hopkins Breast Cancer Center. September 30, 1999, Baltimore, MD. **

Gaston-Johansson, F. (1999) "The Effects of a Coping Strategy Program on Quality of Life and Mortality." Poster Presentation: International Association for the Study of Pain 9th World Congress on Pain, Vienna, Austria – August 22 – 27, 1999.**

Gaston-Johansson, F. (1999). "Fatigue, Pain, and Depression as Predictors of Health Status Breast Cancer Patients." The Joint Research Conference hosted by The University of Maryland School of Nursing & Johns Hopkins University School of Nursing - Poster Presentation. University of Maryland at Baltimore. April 9, Baltimore, MD. (Regional) **

Gaston-Johansson, F. (1998). "Fatigue, Pain, and Depression as Predictors of Health Status in Breast Cancer Patients." American Academy of Nursing 25th Anniversary Meeting & Conference - Breakthroughs in Nursing: Poster Presentation. Oct/Nov, Acapulco, Mexico.**

Gaston-Johansson, F. (1997) "Coping and Health Status in Women with Breast Cancer." Pain Management: Transdisciplinary Care for the 21st Century Clinical Meeting. Eight Annual Conference, Las Vegas, Nevada, September 18-21. American Academy of Pain Management. Poster.**

Gaston-Johansson, F., Kennedy, J., Ohly, K., and Fall-Dickson, J. (1997). "Pain, Anxiety, Depression, Health Status and Coping in Breast Cancer Patients." Era of Hope, The Department of Defense Breast Cancer Research Program Meeting, Washington D.C. October 31 - November 4. **

Funding Applied for Based on this Research
Principal Investigator, "Symptom Distress and Coping in Older Women with Breast Cancer." Submitted to the National Institutes of Health for funding, $1,958,458.00. Project scheduled to begin January 2002 and conclude December 2005 (Pending).

Gaston-Johansson, F. - Co-Investigator and Project Director for Johns Hopkins University, "Developing a Training program in Breast Cancer Research to Decrease the Disparity of Morbidity and Mortality in Underserved/Minority Women." Funded by the U.S. Department of Defense (Proposal #BC004074), $998,658.00. June 2001 – July 2005. Awarded to Winston-Salem State University (WSSU), Sylvia Flack serving as Principal investigator and Project Director for WSSU.

Gaston-Johansson, F. – P.I., "Global Health Promotion Minority Research Program" (Collaborating countries: Sweden, South Africa, and Israel). Funded by NIH/ Fogarty International Center. Awarded 1999-2003, $685,365.00. Grant #1T37 TW00108.

Gaston-Johansson, F. – P.I. "A Coping Program for Older Women with Breast Cancer." Submitted to National Institutes of Health. Funding requested July 1999. Funding period 1999-2003, $1.6 million.

Bakos, A., P.I., Gaston-Johansson, Co-invest. - "Determinants of Diagnostic Follow-up After Inconclusive Screening Mammography." Predoctoral Fellowship: Funded by Department of the Defense - $40,000. Grant #BC971902.

Fall-Dickson J., P.I., Gaston-Johansson, Co-invest. - "The Symptom Experience of Stomatitis & Associated Oral Pain in a Breast Cancer Autologous Bone Marrow Transplant Population. American Cancer Society Doctoral Scholarship in Cancer Nursing ($8,000 x 4 years)

Degrees Obtained
Jane Fall-Dickson: "Acute Oral Pain Experience of Breast Cancer Autotransplant Patents with Stomatitis." Johns Hopkins University School of Nursing. Completion of PhD in Nursing in March 2000.

Alexis Bakos: "Determinants of Diagnostic Follow-up after Inconclusive Screening Mammography." Johns Hopkins University School of Nursing. Completion of PhD in Nursing in March 2000.

Employment and Research Opportunities

Dr. Gaston-Johansson has been appointed Visiting Professor of Nursing at Göteborgs Universitet School of Medicine in Sweden (Appendix 11). She has developed research programs related to symptom evaluation and management of patients suffering from the side effects of cancer treatment.

(9) CONCLUSIONS

A Comprehensive Coping Strategy Program was found to be effective in reducing symptoms (nausea, and nausea combined with fatigue) caused by cancer therapy such as high dose chemotherapy, and ABMT in Breast cancer patients. The CCSP also was successful in improving the breast cancer patient's quality of life. The CCSP may decrease mortality in these patients, however this latter statement should be taken with caution since many of the patients are still alive. Our data supports the CCSP as an effective treatment strategy.

(10) RESULTS OF EXTENSION OF PROJECT

Only 42 patients of 110 had died as of May 22, 2000 (21 in the treatment group and 21 in the control group). Three manuscripts have been submitted for publication. Patients will continue to be followed as part of the Johns Hopkins Hospital Oncology Center procedure. These data information will be made available to the project for continued follow-up.

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Appendix 1

A Comprehensive Coping Strategy Program

A Comprehensive Coping Strategy Program

Presentation: A variety of teaching strategies are used to present the Comprehensive Coping Strategy Program (CCSP) to help promote and maintain breast cancer ABMT patient and PCG interest. Patients, particularly in clinical settings, are likely to experience a range of physical and psychological factors, such as pain, fatigue and anxiety resulting from high psychological stress, which compete with the educator for their interest levels 43. Consideration was also given to providing the best match between specific content areas and the most appropriate teaching. Oral communication (lecture) has been found most effective in establishing rapport and in teaching new knowledge such as preparatory information, while slide tapes are especially beneficial for abstract concepts. Videotapes are most effective in situations when learning step-by-step procedures with movement is required, such as relaxation techniques with guided imagery 43-44. A conference/treatment room is used to present the CCSP. This setting has comfortable chairs and adequate space to practice relaxation. The setting is also appropriate for presenting educational materials.

Preparatory Information: The purposes of the CCSP are presented by the instructor using an overhead. A schematic drawing of the symptoms (pain, psychological distress, and fatigue) that patients are known to experience is presented. The instructor reviews the overhead pointing out the relationship among the different symptoms and how they can influence each other. The instructor summarizes the information by stressing that adequate control of pain can lead to decreased psychological distress and a decrease in physical symptoms other than fatigue. The subjects are told that the information presented is based on the experiences of patients who have successfully undergone ABMT. Handouts that cover appropriate information are reviewed and given to the participants: 1) "Ways in Which You Can Participate in Reducing Pain and Psychological Distress, and; 2) "Some General Ways To Increase Control". The above information is presented by the instructor using simple terminology and principles of learning. In order to make sure that the content is presented in a standardized manner, a detailed script and specific overheads are used by the instructor to present this material.

Treatment of Pain: Theoretical Considerations: This part of the CCSP is a slide presentation with an accompanying tape. Interaction between the instructor and the participants is also encouraged. Information covered include the following topics: definition of pain; the three components of pain; a brief explanation of the Gate Control Theory and; theoretical reasons why increasing control through use of coping self-statements and relaxation with imagery can relieve pain and emotional distress. A handout, titled "Ways in Which You Can Participate In Reducing Pain" is reviewed by the instructor and given to the participants at the end of the session. Colorful slides of simple pictures that symbolize neuro-physiological structures are used when the Gate Control Theory is presented.

Cognitive Restructuring: This segment of the CCSP is also a slide presentation with accompanying tape. This information focuses on the avoidance of catastrophizing, distorted thinking and the use of positive coping self-statements. Cognitive restructuring is directed at modifying thought processes in order to lessen negative sensations and psychological distress. The subjects are taught to conduct an internal dialogue with themselves, which directs and refocuses their attention and thinking. This includes descriptions of unproductive catastrophizing statements made by people experiencing discomfort and distress, and then alternatives that may prove more useful in coping. This includes statements such as "I feel relaxed", "I am in control and can handle this situation" and "I know any discomfort I may feel won't last forever". Two handouts, titled "15 Styles of Distorted Thinking to

Avoid", and "15 Positive Coping Self-Statements," will be reviewed by the instructor and given to the participants.

Relaxation With Imagery: This part of the CCSP is presented on video-tape in a participant-modeling format in which each component of relaxation will be briefly presented, described and demonstrated. The treatment includes a brief progressive muscle relaxation procedure with tense-release cycles being used with specific muscle groups (face, neck and shoulders, stomach and chest, arms and legs). Following these cycles, cue-controlled relaxation will be used involving deep breathing and saying the word "relax" to begin to develop an association between a state of relaxation and these cues. With practice, the cues can then be used to achieve a state of relaxation in a much shorter period of time. Imagery is introduced into the relaxation exercise and participants are permitted to choose the imaginary scene. At the end of the session, the instructor reviews two handouts and gives them to the participants. The handouts are: "Learning and Using Relaxation Therapy" and "Benefits of Relaxation Therapy". The instructor will also give the patient and PCG a small hand-held audiotape recorder (Walkman) with two sets of earphones and an audiotape. The purpose of the tape is to guide the participants in active participation in the relaxation exercise. The participants are instructed to review all handouts and to practice the relaxation exercise, using the 15 minute audiotape at least every day and prior to stressful events. The subjects are instructed how to review the handouts and record their use of the audiotape in a diary.

Reinforcement of CCSP: The reinforcement of the CCSP includes review of the patients and PCGs diaries, responding to any questions that the subjects have concerning the CCSP, measuring relaxation during pre and post reinforcement of the CCSP, reviewing all handouts with the subjects, and having the subjects listen to the 15 minute audiotape with the relaxation exercise with imagery.
Reinforcement of the CCSP takes about 30 minutes.

Appendix 2

Figure 1

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Figure 1

Effectiveness of a Comprehensive Coping Strategy Program (CCSP) on Health Status and Quality of Life of Patients with Metastatic Breast Cancer Receiving Autotransplant (ABMT):1995-1998

(A Collaborative Intervention Study by the Johns Hopkins Medical Institutions, Johns Hopkins Hospital and Johns Hopkins School of Nursing)

(Sponsor: US Armed Force Medical Services)

Participation Rate and Follow-up

Baseline

Control	CCSP
68	70

138

142 — # Patients assigned to Study

Completed Baseline Questionnaires
Participation Rate : 97.2%

4 — Declined Participation

During Hospitalization

Control	CCSP
58	52

110

Completed Study

Too ill to complete questionnaires — 10
ABMT Cancelled — 8
Deaths — 3
Withdrew — 7

Post-Hospitalization Follow-up (>=12 months post-ABMT)
(up to 15th August 1998)

Control	CCSP
35	38

73

70
3

27
13

Follow-up not yet scheduled
Deaths

Completed Study

Completed Baseline and 1 year Follow-up Questionnaires

Follow-up rate(s):

Baseline ---> 1+ year F/U

Numerator	73
Denominator (138-27-8-16 deaths)	87
F/U Rate (73/87)	83.9%

Baseline , Hosp.., 1+ year F/U

Numerator	70
Denominator (110-27-13 deaths)	70
F/U Rate (70/70)	100.0%

Patient Recruitment Year

Year	
1995	36
1996	44
1997	38
1998	20

Updated: 1st September, 1998 (JN090198: d:\ssiz1c)

Appendix 3

Fatigue, Pain, and Depression in Pre-Autotransplant Breast Cancer Patients

Fannie Gaston-Johansson, DrMedSc, RN, FAAN
Jane M. Fall-Dickson, RN, MSN, AOCN
Alexis B. Bakos, RNC, MSN
M. John Kennedy, MB, FRCPI

Fatigue, Pain, and Depression in Pre-Autotransplant Breast Cancer Patients

PURPOSE: The purpose of this study was to determine the influence of fatigue, pain, and depression on health status in breast cancer patients who had completed adjuvant chemotherapy and were scheduled for autologous bone marrow/peripheral blood stem cell transplant (AT).

DESCRIPTION OF STUDY: A descriptive, correlational design was used. A convenience sample of [illegible] women with stages II, III, and IV breast cancer was recruited. The setting was an urban National Cancer Institute designated comprehensive cancer center located in the Eastern United States. Standardized questionnaires and the Gaston-Johansson Painometer (POM) were used to measure the variables. The subjects completed questionnaires in the outpatient clinic. Relationships between the multiple dimensions of fatigue and pain, depression, and health status were examined. Hierarchical regression techniques were used to determine the variance in health status accounted for by fatigue, pain, and depression.

RESULTS: The subjects were age [illegible] to [illegible] years (*Mean* = 45, SD = [illegible]) and primarily were married, white, Protestant, college educated, employed in a professional position, and had an average yearly household income of equal to or greater than $50,000. All subjects had previously received surgery and chemotherapy. Ninety-one percent of the participants reported fatigue as measured by the Fatigue Visual Analogue Scale. Forty-seven percent of the participants reported pain as measured by the Gaston-Johansson POM visual analogue scale. Fifty-four percent of the participants reported depression ranging from mild to severe/high. Subjects reported a mean total perceived health status rating of 50.23 (SD 10.79). Fatigue, pain, and depression were all significantly correlated to each other and to total health status. Depression ($P < .001$) and pain ($P < .01$) significantly accounted for 64% (adjusted $R^2 = .60$) of the variance in total health status. Fatigue ($P < .05$) and depression ($P < .001$) accounted for 42% (adjusted $R^2 = .36$) of the variance in the perception of health status.

CONCLUSIONS: Women with breast cancer previously treated with chemotherapy and awaiting AT may experience fatigue, pain, depression, and alterations in health status. Pain and depression had a significant impact on a woman's total health status, whereas depression and fatigue had an influence on perceived health status. Of the different dimensions of health status, one's perceptions of health status had the strongest correlation to total health status ($r = .84$, $P < .001$). Healthcare professionals need to be aware of the effects of multiple symptoms on health status and to provide appropriate care to alleviate them.

KEY WORDS: Adjuvant chemotherapy, Breast cancer, Depression, Fatigue, Health status, Pain

It is estimated that 175,000 women will receive diagnoses of breast cancer in the United States in 1999; 43,300 women are predicted to die from this disease.[1] Survival rates in breast cancer correlate inversely with the extent of disease. Ten-year survival rates of 65% to 80% for women with disease confined to the breast decrease to a median survival rate of approximately 2 years and a 2% to 5% probability of 5-year disease-free survival for women with metastatic disease.[2] Mastectomy followed by adjuvant chemotherapy (chemotherapy) for breast cancer is one treatment modality developed in response to the challenge of extending disease-free survival and survival. However, multiple symptoms, such as fatigue, pain, and depression, result from the treatment and may have significant effects on the patient's health status. The purpose of this study was to determine whether fatigue, depression, and pain were significant predictors of health status in breast cancer patients who had completed chemotherapy, and were awaiting autologous bone marrow/peripheral blood stem cell transplant (AT). The study had the following research objectives: 1) to describe the prevalence and severity of fatigue, pain, depression, and alterations in health status in breast cancer patients with metastatic disease; and 2) to determine

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This research was supported by Department of Defense grant # DAMD 17-94-J-4068.

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CANCER PRACTICE *September/October 1999, Vol. 7, No. 5*
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whether fatigue, pain, and depression are significant predictors of health status.

Literature Review

Fatigue

Fatigue is the most commonly reported symptom associated with cancer[3] and is a major debilitating symptom that can have a dramatic effect on the lives of patients with breast cancer.[4] The nature of fatigue is complex, has been described by patients as weakness, weariness, sleepiness, tiredness, lack of energy, exhaustion, lethargy, and malaise,[5] and may be a symptom of many diseases.[6] Aistars[7] conceptualized fatigue as a response to continual stress related to multiple physiologic, psychological, and situational factors that are part of the disease and its treatment. This conceptualization was supported by findings of Blesch et al[8] in a study examining correlates of fatigue in people with breast or lung cancer. Fatigue was described from a multidimensional perspective: pathophysiologically as an indicator of functional or metabolic disorder; physically with regard to a decrease in physical performance; and psychologically as it relates to anxiety, depression, or boredom.[8]

Fatigue is a serious iatrogenic side effect associated with chemotherapy, with cell destruction end products, nausea, and vomiting thought to be contributing factors.[9] Chemotherapy-related fatigue is cyclical, usually beginning 1 to 2 weeks after chemotherapy administration in conjunction with the hematologic nadir, decreasing, and then beginning with the following subsequent cycle.[10] Piper et al[11] noted that chemotherapy that crosses the blood-brain barrier may produce fatigue. Sitzia and Huggins[12] reported a mean incidence of 89% in a sample of breast cancer patients treated with cyclophosphamide, methotrexate, and 5-fluorouracil. Potempka[13] in a review of nursing literature from 1978 through 1993 focusing on chronic fatigue in cancer patients receiving chemotherapy, found 18 reports of fatigue prevalence, intensity, and correlates. Prevalence estimates derived from several of these fatigue studies ranged from 80% to 99%.[13] Fatigue may lead to patient abandonment of treatment, limited doses of chemotherapy, and decreased patient quality of life (QOL).[5]

Research conducted by Blesch et al[8] revealed that scores on the Profile of Moods States subscales for fatigue-inertia, tension-anxiety, depression-dejection, anger-hostility, and confusion-bewilderment were significantly correlated with self-rated fatigue intensity and were inversely correlated with the vigor-activity subscale score in a sample of patients receiving chemotherapy, radiation therapy, or both for breast or lung cancer. Similarly, Irvine et al[14] found that fatigue covaried with symptom distress, mood disturbance, and loss of ability to perform usual functional abilities and was not significantly correlated either with duration of disease status or with stage of disease. Understanding the etiology of fatigue and how to manage this symptom effectively is a challenge for oncology practitioners and researchers,[15] as well as for patients.

Pain

Pain has been shown to be a significant problem for breast cancer patients.[16-18] Pain may be acute, as experienced before diagnosis or after lumpectomy or mastectomy and axillary node dissection, or it may be chronic and long-term in nature.[19] Treatment-related breast pain from surgery and chemotherapy is related to breakdown of the skin integrity. This treatment-related pain has been characterized as irritating,[19] constricting, burning, or throbbing sensations localized to the posterior arm, axilla, and anterior chest wall.[20,21]

Pain has been reported in 47% of breast cancer patients receiving treatment in the outpatient setting,[17] with the majority of patients having treatment-related pain from postsurgical neuropathic pain syndrome (56%) and bone metastasis (26%). Patients rated their pain as moderate to severe on a daily basis. Baron[20] reviewed the literature regarding sensory alterations experienced after breast cancer surgery. Results showed that many patients experienced a variety of sensory alterations in the breast area and the anatomic areas located near the breast—the chest wall, arm, and axilla.[20] These sensations, which included pain, were often reported as severe and distressing.[20]

Patients who experience cancer pain are found to have significantly more depression and anxiety, and greater decreases in QOL scores than pain-free patients.[22] Cancer survivors have noted that fatigue was a precursor to decreasing their tolerance to pain and that pain is a physical symptom related to increasing fatigue.[23]

Depression

Depression is a common response to the diagnosis of and treatment for breast cancer.[24,25] Massie[26] found from an analysis of 20 years of research regarding depression in cancer patients that approximately 25% were depressed and up to 50% exhibited some symptoms of depression.

Coscarelli-Shag et al[27] identified the following major sources of psychological distress for breast cancer patients at 1-month postdiagnosis: 1) anxiousness while waiting for test results and having to undergo additional diagnostic tests; 2) worries over whether the cancer was progressing; 3) concern about ability to take care of self; and 4) concern about how the family would manage if the patient died. Chemotherapy represents a prolonged threat to a patient's mortality and functioning leading to additional psychological distress after breast surgery. Elevated levels of depression and anxiety may persist in a minority of breast cancer patients even years after the diagnosis.[28]

Spiegel et al[29] explored the relationship between pain and depression in two samples of patients with cancer: 1) 96 subjects, 48 in the high-pain group and 48 in the low-pain group; and 2) 35 patients with metastatic carcinoma of the breast. Prevalence of depression was found to be significantly higher in the high-pain group rather than in the low pain group.[29] Pain intensity was also found to correlate significantly with fatigue, vigor, and total mood disturbance. Pain frequency correlated significantly with fatigue, vigor, and depression.[29] Aass et al[30] investigated the preva-

lence of anxiety and depression in 716 cancer patients and found that the prevalence of depression was 9%, with age or gender having no influence on the occurrence of depression.[30] The prevalence of depression increased with distant metastases, with the time period of less than 1 month from diagnosis, and was seen with a relapse or disease progression.[30]

Perceived Health Status

Physical and mental health and social and role functioning are important components of perceived health status.[31] Frequency and severity of pain, psychological distress, and fatigue influence a patient's perceived health status, QOL, and length of hospital stay.[32] Fatigue has been linked with impairment in cognitive functioning and impaired perception and thinking ability.[5] Lee et al,[33] in a study of women's responses to environmental demands, found that depression or anxiety were more significantly related to both fatigue and vitality than were external stresses. A patient's beliefs about her health status have been shown to be an important determinant of health outcomes.[34]

Methodology

Sample and Setting

This study used a descriptive, correlational design. A convenience sample of 127 women with stage II, III, or IV breast cancer who had undergone mastectomy, completed chemotherapy, and were scheduled for AT were recruited for the study. The time between chemotherapy completion and AT varied, and no data were collected regarding the length of time between these periods. The setting was an urban National Cancer Institute-designated comprehensive cancer center located in the Eastern United States. The study was approved by the institutional review board before participant accrual. All participants were recruited by either the physician co-principal investigator (PI) or the bone marrow transplant clinical nurse specialist coinvestigator during a regularly scheduled visit to the Medical Oncology Outpatient Clinic. Written informed consent was obtained from each participant.

The subjects completed the questionnaires in a quiet, comfortable room located in the outpatient clinic. Patients were informed that they could take a break at any time during data collection. The bone marrow transplant clinical nurse specialist provided the baseline questionnaires, answered participants' questions, and retrieved the questionnaires after completion. It took approximately 1 hour for the subjects to complete the questionnaires.

Instrumentation

The Sociodemographic Form was used to collect demographic and clinical data. Fatigue was measured using the Piper Fatigue Scale (PFS)[35] and the fatigue Visual Analogue Scale (VAS). The PFS was designed to measure fatigue as a multidimensional phenomenon. Therefore, use of the PFS is congruent with the conceptual framework of this study, which recognizes that fatigue is a multidimensional symptom.[11] Subjective dimensions of this scale include perceptions regarding the temporal, sensory, affective, and severity components of fatigue. Piper[35] stated that in this model of fatigue, ". . . subjective perception was believed to be key to understanding how fatigue might vary between healthy and ill individuals." The objective dimension includes signs of fatigue that could be validated by physiologic, biologic, and behavioral means. The scale consists of 41 horizontal VAS items measuring four dimensions of subjective fatigue: 1) the temporal dimension (5 items relating to timing, frequency, pattern, and duration of fatigue); 2) the intensity/severity dimension (12 items relating to severity, distress, and degrees of disruption in activities of daily living); 3) the affective dimension (5 items relating to the emotional meaning of fatigue); and 4) the sensory dimension (19 items relating to the physical, emotional, and mental symptoms of fatigue).[35]

Subjects using the PFS are asked to respond to items in terms of how they feel now. Anchors on the VAS vary depending on the item. Individual subscale scores are calculated by measuring each VAS item with a 100-mm ruler from the left end to the subject's mark, summing all items within the subscale, then dividing the sum by the number of items on the subscale to obtain a mean value. A total fatigue score is calculated by summing the four scores and dividing by four. In a preliminary study by the PI, Cronbach's alpha estimated for the four subscales in AT patients ranged from .83 to .98.

The fatigue VAS is a 100-mm vertical visual analogue scale anchored with "completely exhausted" and "no fatigue." The subject marks with a horizontal mark through the vertical line indicating the degree of fatigue that she is currently experiencing. Reliability and validity of the fatigue VAS have been demonstrated through the VAS scales used on the PFS.

Pain was measured using the Gaston-Johansson Painometer (POM), which was designed to assess patients' overall pain intensity and intensity of the sensory and affective components of pain, as well as the quality and location of pain.[36] The POM is a hard, white plastic tool that measures 8 in long, 2 in wide, and 1 in thick. It is lightweight and is held easily by the subject. A 100-mm VAS with a moveable marker (POM-VAS) is located on the back side of the POM (Fig 1). A list of 15 sensory and 11 affective pain descriptors is located on the front side of the POM (Fig 2). An intensity value (from a low of 1 in to a high of 5 in) is predetermined for each sensory word (cramping, dull, shooting, sharp, pressing) and affective word (nagging, terrifying, miserable, torturing, unbearable) located on the POM. A maximum score of 36 can be obtained for the sensory component of pain and a maximum of 34 for the affective component. A total score can be obtained by adding the sensory and affective scores. Test-retest reliability, concurrent validity, and construct validity have been demonstrated.[36] The POM questionnaire was used to record pain intensity, pain quality, pain locations, duration (whether the pain was continuous or periodic), and length of present pain episodes.
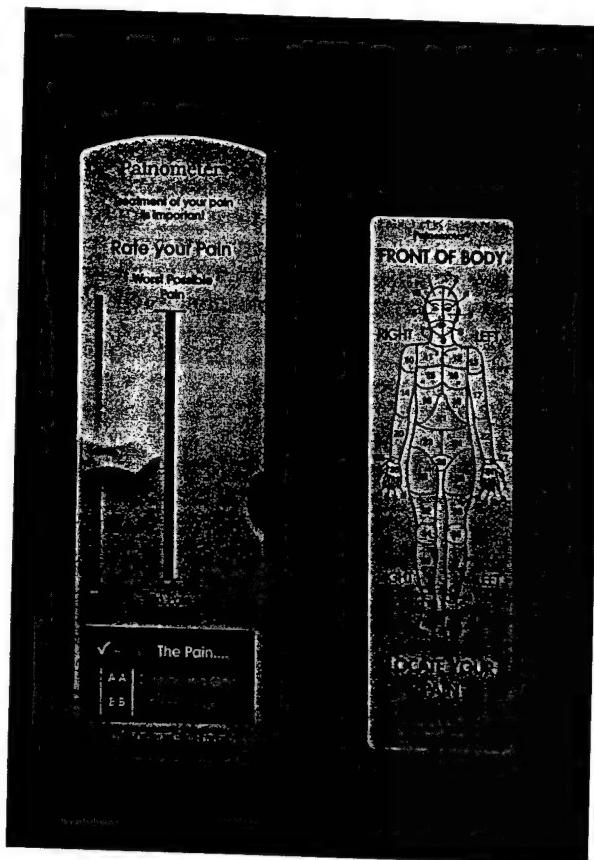
Figure 1 Side I of the Gaston-Johansson Painometer (US Patent 5,018,256, May 28, 1991).

The Beck Depression Inventory (BDI) was used to measure depression in subjects. The BDI consists of 21 items that describe particular symptoms of depression.[37] Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores may range from 0 to 9 (normal), 10 to 15 (mild depression), 16 to 23 (moderate depression), and 24 to 63 (severe depression). The total possible score (range 0–63) is obtained by summing the 21 responses. Reliability and validity have been reported for the BDI.[37]

Perceived health status was measured by the Medical Outcomes Study Short-form General Health Survey.[31] This 20-item survey assesses physical functioning (6 items), role functioning (2 items), social functioning (1 item), mental health (5 items), health perception (5 items), and pain (1 item).[31] Physical functioning refers to limitations in a variety of physical activities. Role and social functioning are defined as limitations related to health problems. Mental health is assessed in terms of both psychological distress and well-being. Health perception is assessed by the patients' perceptions of their own health in general, and pain refers to differences in physical comfort. The total health perception score is obtained by summing all of the scores of the mental health scales for a possible score range of 0 to 91.[31] The pain and social functioning subscales have a possible score range of 1 to 6. The role functioning subscale has a possible score range of 0 to 6. The physical functioning subscale has a possible score range of 1 to 18. The

mental health subscale has a possible score range of 1 to 30, and the health perception subscale has a possible score range of 1 to 25.

Construct validity was demonstrated by showing that poor health was significantly greater ($P < .001$) in a patient sample than in a general population sample regarding physical and role functioning, mental health, and health perceptions. Statistically significant correlations ($P < .01$) were found among all health measures. Cronbach's alpha estimated for the four multi-item scales ranged from .81 to .88.[31] In a preliminary study by the PI, Cronbach's alpha for the Medical Outcomes Study Short-form General Health Survey in AT patients ranged from .58 to .98 for the subscales.

Data Analysis

Measures of central tendency were used to describe the sample and responses to the instruments. Correlations among multiple dimensions of fatigue and pain, depression, and health status were analyzed using Pearson's product moment correlations and Spearman's rank correlation, as appropriate. Hierarchical multiple linear regression techniques were used to determine the predictors of total health status and perceived health status.

Figure 2 Side II of the Gaston-Johansson Painometer (US Patent 5,018,256, May 28, 1991).

Results

Sample Characteristics

The sample of 127 women subjects with breast cancer, ranging in age from 22 years to 60 years (mean (*M*) = 45 ± SD 7.6), was composed of 111 whites (87%), 11 African Americans (9%), and 4 other minorities (3%) (Table 1). Most of the subjects were married (73%) and living with a spouse (72%), with an average yearly household income of equal to or more than $50,000 (58%). The sample was primarily Protestant (46%),

Table 1. *Demographic Characteristics of the Sample (n = 127)**

Demographic Characteristics	n	%
Gender		
Female	127	100
Age (yr)		
Mean	45	
SD	7.6	
Range	22–60	
Ethnicity		
White	111	87.4
African American	11	8.7
Other minorities	4	3.1
Marital status		
Married	93	73.2
Single	18	14.2
Divorced	14	11
Separated	1	0.8
Education completed		
High school	23	18.1
Some college	35	27.6
College graduate	39	30.7
Graduate degree	28	22
Religion		
Catholic	31	24.4
Protestant	59	46.5
Jewish	9	7.1
Other	20	15.1
None	4	3.1
Patient lives with		
Spouse	91	71.7
Other	14	11
Self	20	15.7
Average yearly income		
<$50,000	39	30.7
≥$50,000	74	58.3
Occupation		
Professional	72	56.7
Nonprofessional	42	33.1
Work status		
Employed	85	66.9
Unemployed	37	29.1

*Note: Some patients chose not to answer all questions. Missing data excluded for percentage computation where applicable.

college educated (53%), and employed (67%) in a professional position (57%). All subjects had received previous surgery and chemotherapy.

Fatigue

Ninety-one percent of the participants reported fatigue as measured by the Fatigue VAS. Subjects reported a mean total Fatigue VAS rating of 28 (SD 25.5). The mean total PFS rating was 31.3 (SD 20). Multiple dimensions of fatigue scores are presented in Table 2.

Pain

Forty-seven percent of the participants reported pain as measured by the POM-VAS. All mean pain intensity scores for the subjects who experienced pain were low: affective pain intensity score was 1.72 (SD 3.87); sensory pain intensity score was 2.34 (SD 3.72); total pain intensity score was 4.05 (SD 6.94); and overall pain intensity score on the POM-VAS was 8.4 (SD 16.76) (Table 2). Although the mean pain scores for sensory, affective, total intensity and overall intensity were low, the range of reported scores was wide indicating that some subjects did experience moderate to severe pain intensity (Table 2).

Depression

Fifty-four percent of the participants reported depression. The mean depression score was 10.92 (SD 7.30) (Table 2). Depression ranged from mild (30%), to moderate (19%), to severe/high (5%), with 46% of the subjects reporting normal scores.

Health Status

Subjects reported a mean total perceived health status rating of 50.73 (SD 10.79) with a possible range of 0 to 91

Table 2. *Mean Fatigue, Pain, and Depression Ratings of Patients with Breast Cancer (n = 127)*

Variables	Mean	SD	Range
Fatigue			
Temporal dimension	35.20	35.59	0–79
Intensity/severity dimension	20.76	19.77	0–74
Affective dimension	34.38	25.26	0–92
Sensory dimension	36.52	21.06	0–88
Total	31.26	19.98	0–87
Visual Analogue Scale	28.25	25.46	0–97
Pain			
Affective dimension	1.71	3.87	0–28
Sensory dimension	2.34	3.72	0–22
Total	4.05	6.94	0–44
Visual Analogue Scale	8.43	16.76	0–100
Depression	10.92	7.30	0–37

(Table 3). A high mean (*M*) rating was reported for mental health (*M* 21.95; SD 4.59). A moderate mean rating was reported for pain (4.19; SD 1.27) , social functioning (4.74; SD 1.36), and health perception (15.10 ; SD 4.95). A low mean rating was reported for physical functioning (3.82; SD 1.70). The lowest mean was reported for role functioning (.84; SD .89).

Correlations Among Variables

Significant correlations were observed among pain and fatigue (.34; $P < 0.001$), pain and depression (.25; $P < 0.01$), and depression and fatigue (.58; $P < 0.001$). Significant correlations were also observed between health status and pain (.32; $P < 0.001$), fatigue (VAS fatigue $-.33$; $P < 0.001$), sensory ($-.60$; $P < 0.001$) and sensory/intensity fatigue ($-.61$, $P < 0.001$).

Variance in Health Status

The variance in health status was determined after controlling for demographic variables. Depression ($B = -.94$; $\beta = -.65$; $P < .001$) and sensory pain ($B = -.53$; $\beta = -.19$; $P < .01$) accounted for 64% (adjusted $R^2 = .60$; $F = 15.37$) of the variance in total health status. Depression ($B = -.94$; $\beta = -.65$; $P < .001$) and affective pain ($B = -.45$; $\beta = -.17$; $P < .05$), accounted for 63% (adjusted $R^2 = .59$; $F = 14.90$) of the variance in total health status. Fatigue ($B = .04$; $\beta = -.19$; $P < .05$) and depression ($B = -.27$; $\beta = -.41$; $P < .001$) accounted for 42% (adjusted $R^2 = .36$; $F = 6.46$) of the variance in the perception of health status.

Discussion

The sample was composed of a select group of primarily highly educated, married white patients, who were employed in professional occupations with average yearly incomes greater than $50,000. This convenience sample places limitations on the study. Therefore, caution should be exerted in generalizing these results to other breast cancer patients in the ambulatory setting awaiting AT. In addition, not having data regarding the length of time between completion of adjuvant chemotherapy and baseline data was a limitation.

Although participants overall exhibited low to moderate levels of pain, depression, and fatigue, a large number of women reported multiple symptoms that were significantly related to each other. Almost all (91%) of women reported feelings of fatigue, which were highly significantly correlated with overall total health status. The dimensions of fatigue that most highly correlated with total health status were the intensity/severity and sensory dimensions. Not surprisingly, these are the dimensions that encompass the degrees of disruption in activities of daily living and the physical, emotional, and mental symptoms of fatigue that signal a reduction in health status.

Although participants rated their pain as low, more than 50% of the women reported pain. A continuous low-grade pain can interrupt activities of daily living and decrease one's health. Interestingly, pain was significant, but only slightly correlated with depression.

Depression was a frequently cited symptom of more than half of the respondents with almost a quarter of the subjects reporting moderate to high levels of depression. Depression was highly correlated with fatigue, particularly with the intensity/severity and sensory dimensions of fatigue. Consequently, fatigue's effect on an individual's inability to carry out various daily activities is highly associated with depression. Research conducted by Aass et al[30] determined that fatigue increased the odds of the occurrence of depression. Depression was also highly negatively correlated with total health status, specifically with the social functioning and perception of health status domains. Other investigators have also reported that long after a patient has undergone mastectomy followed by chemotherapy, fatigue, pain, and depression continue to alter health perception.[38] Thus, the multiplicity of symptoms may have important consequences for health outcomes after chemotherapy. Previous studies using instruments that incorporated constructs of both depression and fatigue were limited in their ability to discriminate between the two symptoms.[8] Depression and pain accounted for a large amount of the variance in the regression model and were most predictive of total health status. The results of this study suggest that fatigue is associated with total health status through perception of health status.

Clinical Implications

The results of this study should serve as an important reminder to oncology practitioners that the majority of women undergoing mastectomy followed by chemotherapy continue to experience symptoms after treatment has ended. These patients may not receive any further validation of their symptom experience. Although most patients reported low to moderate symptom severity levels, the presence of fatigue, pain, and depression in some breast cancer patients requires vigilant assessment and intervention. Patient teaching materials that instruct patients to use symptom-management strategies, such as relaxation with

Table 3. *Mean Health Status Ratings of Patients with Breast Cancer (n = 127)*

Items on MOS-SF*	Mean	SD	Range
Pain	4.20	1.27	1–6
Physical functioning	3.82	1.70	0–6
Role functioning	.84	.90	0–2
Social functioning	4.74	1.36	1–6
Mental health	21.95	4.59	8–30
Health perception	15.11	4.95	5–25
Total	50.73	10.79	18–72

*MOS-SF, Medical Outcomes Study Short Form General Health Survey.

guided imagery, are congruent with this viewpoint. Interventions that change how breast cancer patients perceive their health status may also reduce symptom severity and positively affect their total health status. Self-care procedures, such as the use of positive coping strategies and avoidance of negative thinking, may prove to be an efficient and effective means of alleviating symptoms.

Researchers investigating the symptom experience and health outcomes of patients have advocated assessing the patient's perception and evaluation of symptoms, as well as the patient's response to symptoms.[39] Evidence that a subject's perception of her health status is highly correlated with her actual health status supports this approach. Patients are the key source of information about their symptom experience in relation to their overall health.

The time period preceding the AT treatment for breast cancer patients is scheduled tightly with procedures, laboratory tests, and educational sessions. Symptoms of pain, fatigue, and depression may not be assessed consistently in this fast paced ambulatory care environment. Future research should focus on improving assessment strategies for these symptoms and testing interventions planned to alleviate pain, fatigue, and depression and to improve the health status of breast cancer patients who are awaiting AT.

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Appendix 4

Pain, Psychological Distress, Health Status, and Coping in Patients with Breast Cancer Scheduled for Autotransplantation

Pain, Psychological Distress, Health Status, and Coping in Patients With Breast Cancer Scheduled for Autotransplantation

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Purpose/Objectives: To describe pain, psychological distress, health status, and coping that patients with breast cancer who were scheduled for autotransplantation experienced; the strength and direction of relationships among pain, psychological distress, health status, and coping; and the percentage of variance within the concept of health status that age, pain, psychological distress, and coping.

Design: Descriptive, correlational.

Setting: An urban, National Cancer Institute-designated comprehensive cancer center located in the eastern United States.

Sample: A convenience sample of 83 female patients with breast cancer scheduled for autotransplantation. The population age ranged from 22-59 years ($\overline{X}$ = 44.47 years) and was comprised of 72 (88%) Caucasians, 6 (7%) African Americans, and 4 (5%) from other minorities.

Methods: An oncology clinical nurse specialist in the outpatient medical oncology clinic collected the data during a regularly scheduled visit approximately 20 days prehospitalization for high-dose chemotherapy and autotransplantation. Data were collected using a demographic data form and self-report instruments (Gaston-Johansson Painometer®, State-Trait Anxiety Inventory, Beck Depression Inventory, Medical Outcomes Study Short-Form General Health Survey, and Coping Strategies Questionnaire).

Main Research Variables: Pain, psychological distress, health status, and coping.

Findings: Although the subjects experienced low pain intensity, the range of reported pain intensity ratings was wide. Pain locations varied but were reported mainly in the vagina, chest, shoulder, and arm. Although subjects reported primarily mild depression and mild state anxiety, the range of depression and state anxiety scores was wide. Coping strategies used most frequently to deal with pain included positive coping statements, diverting attention, praying and hoping, increasing activity level, and ability to control and decrease pain. Subjects reported moderate total health status and low role functioning. Moderate, positive correlations were seen between state anxiety and depression and physical functioning and role functioning. Sixty-five percent of the variance in health status was explained by sensory pain, depression, and catastrophizing.

Conclusions: Patients with breast cancer who are scheduled for autotransplantation may experience pain, psychological distress, and alterations in coping and perceived health status. Total pain intensity, sensory pain, depression, and catastrophizing appear to be important variables related to the patient's perceived health status.

Implications for Nursing Practice: Oncology nurses need to include assessment of pain, psychological distress, health status, and coping in their routine patient assessment prior to autotransplantation to provide appropriate care and make necessary multidisciplinary referrals. Future nursing research should be directed toward the implementation and evaluation of interventions that promote the use of comprehensive coping strategies to decrease pain, anxiety, and depression.

The American Cancer Society estimates that 175,000 new cases of female breast cancer will be diagnosed in the United States in 1999, and 43,300 women will die from this disease (Landis, Murray, Bolden, & Wingo, 1999). Although the five-year survival rate for local stage breast cancer currently is 97%, this rate decreases to 20% when the cancer is diagnosed with distant

metastases (United States Department of Health and Human Services, 1997). Clearly, innovative treatment strategies are needed to increase these survival rates. One such treatment modality is autotransplantation, which exploits the steep dose-response relationship seen in breast cancer through the administration of high-dose chemotherapy followed by rescue with either the patients' own bone marrow or, more frequently, peripheral blood stem cells to avoid lethal myelosuppression (Appelbaum, 1996). This treatment modality has become widespread (Whedon, 1996); more than 5,000 autotransplantations are performed annually worldwide (Buchsel, Leum, & Randolph, 1996).

The purpose of this study was to describe and examine relationships among pain, psychological distress, perceived health status, and coping in patients with breast cancer after treatment with mastectomy and chemotherapy prior to autotransplantation. Assessment of pain, psychological distress, perceived health status, and coping will help healthcare providers understand and provide appropriate care for patients during this phase of treatment. This study examined to what degree pain, psychological distress, and coping were predictors of health status.

Literature Review

Research literature exists regarding the pain, psychological distress, and coping that patients undergoing autotransplantation experience during and after hospitalization (Gaston-Johansson, Franco, & Zimmerman, 1992; Hill et al., 1990; Jenkins & Roberts, 1991). However, there is a paucity of research exploring these variables prior to autotransplantation. Assessment and treatment of patients' emotional state is extremely important prior to transplantation procedures and associated intensive chemotherapy because efforts can be directed at reducing psychological distress and helping patients better cope with the upcoming situation (Gaston-Johansson & Foxall, 1996).

Conceptual Framework

Melzack and Wall's (1982) Gate-Control Theory of Pain and Lazarus and Folkman's (1984) Stress, Coping, and Adaptation paradigm provided the theoretical framework for this study. Pain is defined as a multidimensional sensory and affective experience associated with discomfort (International Association for the Study of Pain, 1979). According to the Gate-Control Theory of Pain, the central system located in the brain can be stimulated by cognitive processes (e.g., past experiences, anxiety, anticipation, attention) that open the gating mechanism and permit the transmission of nociceptive impulses to the brain (Melzack & Wall).

Pain

Several studies have shown that pain was a significant problem for a large number of patients with stage I or II breast cancer (Arathuzik, 1991; Miaskowski & Dibble, 1995a, 1995b). Pain may be acute (as experienced prediagnosis and following lumpectomy or mastectomy and axillary node dissection) or chronic and long-term in nature (Gorrell, d'Angelo, & Bagley, 1988). Patients with breast cancer have characterized this treatment-related pain as

irritating (Gorrell et al.), shooting, throbbing, burning, stabbing, pulling, and tight (Stevens, Dibble, & Miaskowski, 1995). Only one published study could be found that examined the pain that patients with breast cancer experienced and its effects on their lives in the outpatient setting (Miaskowski & Dibble, 1995b). Forty-seven percent of the patients in this study who were receiving treatment in the outpatient setting reported moderate to severe cancer-related pain on a daily basis. The majority of these women had treatment-related pain from postsurgical neuropathic pain syndrome (56%) and cancer-related pain from bone metastasis (26%).

Patients who experience cancer pain have significantly more depression, anxiety, and decreased quality of life (QOL) scores than pain-free patients (Ferrell, Dow, Leigh, Ly, & Gulasekaram, 1995; Ferrell & Funk, 1995; Miaskowski & Dibble, 1995b). Arathuzik's (1994) pilot study found that educating patients with breast cancer in relaxation techniques and cognitive coping skills was effective in decreasing pain. Used separately, these nonpharmacologic approaches have proven to be effective in relieving pain in patients with breast and lung cancer (Arathuzik, 1994; Ferrell-Torry & Glick, 1993; Wilkie, 1990, 1991). However, these approaches have not been evaluated in combination in a randomized controlled clinical trial.

Psychological Distress and Coping

Six psychosocial stages corresponding to the medical management of bone marrow transplant (BMT) have been identified (Brown & Kelly, 1984; Haberman, 1988). The initial two stages—making the decision to undergo BMT and preadmission—are contextually appropriate for this study. The decision-making stage represents a major turning point in patients' lives. Numerous factors influence patients' decisions to undergo BMT. The cost/benefit ratio of possibly achieving increased survival time versus potential acute and chronic negative sequelae is a major factor (Haberman). Uncertainties may linger after this decision-making stage and may be present during the preadmission stage and other stages. The preadmission stage presents patients with breast cancer with unique psychological demands and concerns. Patients may experience stress from numerous sources, such as recent breast cancer surgery, knowledge of a life-threatening diagnosis, and uncertainty regarding the future autotransplantation treatment process and outcome (Jenkins, Linington, & Whittaker, 1991).

Anxiety and depression are common responses to the diagnosis of and treatment for breast cancer (Maraste, Brandt, Olsson, & Ryde-Brandt, 1992; Schain, d'Angelo, Dunn, Lichter, & Pierce, 1993). Meyers et al. (1994) explored the cognitive and emotional functioning of 61 adult patients before, during, and after BMT. Results demonstrated that nearly 40% of the sample experienced significant anxiety pre-BMT. Elevated levels of depression and anxiety may persist in a minority of patients with breast cancer, even years after the diagnosis (Spiegel, 1997). Adjuvant chemotherapy represents a prolonged threat to patients' mortality and functioning, leading to additional psychological distress after breast surgery. One study indicated that 14% of patients who underwent adjuvant chemotherapy after breast-conserving surgeries and mastec-

tomies experienced severe anxiety (Maraste et al.). Coscarelli-Schag et al. (1993) identified the major sources of psychological distress for patients with breast cancer one month postdiagnosis as (a) anxiety while waiting for test results and having to undergo additional diagnostic tests, (b) worries over whether the cancer was progressing, (c) concern about ability to take care of self, and (d) concern about how the family would manage if the patient died. Assessing patients' anxiety and depression during the preadmission period is of paramount importance to provide appropriate interventions and because patients undergoing autotransplantation must adhere to the strict treatment and follow-up protocol schedule.

Coping behaviors are used to manage pain as well as psychological distress (Arathuzik, 1991). Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external or internal demands that are appraised as taxing or exceeding a person's resources (Lazarus & Folkman, 1984). Positive coping strategies refer to internal thoughts and behaviors people use to manage their pain or emotional reactions to the pain and to reduce emotional distress. Coping behaviors may include ability to control pain, use of positive coping statements, and catastrophizing. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future (Keefe et al., 1987; Keefe, Brown, Wallston, & Caldwell, 1989). Although investigators have described coping strategies for pain, few have described the nature of this coping with pain (Arathuzik, 1991; Graffam & Johnson, 1987). Gaston-Johansson et al. (1992) reported that patients undergoing autotransplantation used inadequate coping strategies and experienced little ability to control or decrease their pain. Numerous challenges to coping exist: the change to patient status, potential geographic dislocation, and the preparation of significant others for the possibility of morbidity and death. Issues such as decreased pain tolerance and pain related to procedures, disease, or prior treatment may be evident. Coping issues related to decision making regarding treatment and access to and use of psychological supports may be present. Psychological responses, such as distress, may be operational (Syrjala, 1995).

Perceived Health Status

Frequency and severity of pain, psychological distress, and fatigue influence patients' perceived health status, QOL, and length of hospital stay (Chielens & Herrick, 1990). Patients' beliefs about their health status are an important determinant of health outcomes (Wolcott, Wellisch, Fawzy, & Landsverk, 1986). The health status of patients with breast cancer as well as their past treatment varies (Chielens & Herrick). Assessing the degree of psychological distress, functional status, and role capability in the evaluation of health status is important (Stewart, Hays, & Ware, 1988).

Purpose

The study had the following research objectives.
1. Describe pain, psychological distress, and health status of patients with breast cancer who previously had been

treated with mastectomy and chemotherapy and are scheduled for autotransplantation.
2. Examine the relationships among pain, psychological distress, catastrophizing, coping, and perceived health status in patients with breast cancer.
3. Describe the percentage of variance within the concept of health status that was explained by pain, psychological distress, and coping (i.e., ability to control pain, use of positive coping statements, and catastrophizing).

Methods

The study used a descriptive, correlational design. Inclusion criteria included patients with stage II, III, or IV breast cancer who previously had been treated with mastectomy and chemotherapy and were scheduled to receive an autotransplantation, age equal to or greater than 18 years, and the ability to speak and read English. The setting was an urban National Cancer Institute-designated comprehensive cancer center located in the eastern United States.

Instruments

The **Sociodemographic Questionnaire** gathered information regarding age, gender, race/ethnicity, marital status, educational level, religion, living arrangements, average yearly household income, occupation, work status, and breast cancer stage as verified by the medical record.

The Gaston-Johansson Painometer® (1996) was designed to assess patients' overall pain intensity and intensity of sensory and affective components of pain, as well as the quality of pain. The Painometer is a hard, white, plastic tool that measures eight-inches long, two-inches wide, and one-inch thick. It is lightweight and easy for participants to hold. The front of the Painometer lists 15 sensory and 11 affective pain descriptors, and a 100 mm visual analogue scale (VAS) with a moveable marker (Painometer-VAS) is located on the back. An intensity value (from a low of "1" to a high of "5") is predetermined for each sensory and affective word located on the Painometer-Words. The maximum score for the sensory component of pain is 36, and for the affective component, the maximum is 34. To obtain a total score, add the sensory and affective scores. High correlations were found between the initial and the repeat pain intensity ratings on the Painometer-VAS ($r = 0.88$, $p < 0.001$) and Painometer-Words ($r = 0.84$, $p < 0.001$) (test-retest reliability). Correlations among the Painometer-Words, the McGill Pain Questionnaire ($r = 0.69$, $p < 0.001$), and the Painometer-VAS ($r = 0.85$, $p < 0.001$) supported the concurrent validity of the Painometer-Words. Construct validity was supported for the Painometer by showing that pain scores decreased significantly for the Painometer-Words ($t = 5.53$, $p < 0.001$) and Painometer-VAS ($t = 6.18$, $p < 0.001$) after treatment with pain medication. The Painometer takes about two minutes to complete.

Psychological distress was measured using the **State-Trait Anxiety Inventory (STAI)** (Spielberger, Gorsuch, & Lushene, 1971) and the **Beck Depression Inventory** (BDI, 1970). The STAI, an extensively used measure of anxiety, consists of two separate self-report scales for measuring state and trait anxiety. State anxiety is a transi-

tory emotional response to a stressful situation. Trait anxiety reflects a stable predisposition to anxiety as determined by a personality pattern. Each scale consists of 20 statements that participants rate regarding how they feel in general (trait) and at one particular moment in time (state). Respondents rate themselves in relation to each statement on a Likert-type scale, with score anchors ranging from 1 (not at all) to 4 (very much so). The total score is the sum of all responses, with 20–39 = low anxiety, 40–59 = moderate anxiety, and 60–80 = high anxiety. Scores are reported to be considerably higher under stress conditions than under normal conditions. Spielberger et al. reported test-retest reliability coefficients of 0.73–0.86 and 0.860–0.92 for the trait subscale and coefficients of 0.16–0.54 and 0.83–0.92 for the state subscale. Alpha coefficients estimating internal consistency ranged from 0.83–0.92 for state and 0.86–0.92 for trait anxiety.

The **BDI** was used to measure depression. Subjects responded to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). The total score (0–63) is obtained by summing the 21 responses with the following interpretations: 0–9 = normal, 10–15 = mild depression, 16–23 = moderate depression, and 24–63 = severe depression. The alpha coefficient for the BDI was reported to be 0.84–0.86, with a Spearman-Brown coefficient of 0.93 (Beck; Gaston-Johansson et al., 1992). Test-retest reliability in nonpsychiatric patients ranged from 0.60–0.90 (Beck & Steer, 1984). Concurrent validity of the BDI has been established to range between 0.61 and 0.66 (Beck; Beck & Steer), and construct validity was demonstrated through correlation with the **Minnesota Multiphase Personality Inventory D** subscale (0.75) (Beck).

The **Coping Strategy Questionnaire (CSQ)** developed by Keefe et al. (1987) assessed patients' use of coping strategies. The categories of coping strategies assessed by this measure included (a) diverting attention, (b) reinterpreting pain sensations, (c) ignoring pain sensations, (d) praying and hoping, (e) catastrophizing, and (f) increasing activity level. For each category of coping strategies, six items are listed on the CSQ, with possible total scores ranging from 0–36. Each item is rated on a 7-point scale to indicate how often that strategy is used to cope with pain (0 = never, 3 = sometimes, and 6 = always). CSQ reliability has been demonstrated with alpha coefficients ranging from 0.71–0.85. Cronbach's alpha ranged from 0.71–0.88 in patients receiving chemotherapy. The CSQ also includes two items that measure overall effectiveness of the strategies used by asking subjects to rate on a 7-point scale (with scores ranging from 0–6) how much control they have over the pain and how much they are able to decrease their pain (Keefe, Crisson, Urban, & Williams, 1990). Construct validity was demonstrated by factor analysis (Carey & Burish, 1987; Keefe et al., 1990).

The **Medical Outcomes Study Short-Form General Health Survey (MOS-SF)** (Stewart et al., 1988) was used to measure perceived health status. This 20-item survey assessed physical functioning (six items), role functioning (two items), social functioning (one item), mental health (five items), health perception (five items), and pain (one item) (Stewart et al.). Physical functioning refers to limitations in a variety of physical activities. Role and social

functioning are defined as limitations related to health problems. Mental health is assessed in terms of psychological distress and well-being. Health perception is assessed by the patients' perceptions of their own health in general, and pain refers to differences in physical comfort. The total health perception score is obtained by summing all subscale scores (Stewart et al.) for a possible score range of 0–91. The Pain and Social Functioning subscales have a possible score range of 1–6. The Role Functioning subscale has a possible range of 0–6. The Physical Functioning subscale has a possible score range of 1–18. The Mental Health subscale has a possible score range of 1–30, and the Health Perception subscale has a possible score range of 1–25.

Construct validity was demonstrated by showing that poor health was significantly greater ($p < 0.001$) in a patient sample than a general population sample regarding

Table 1. Sociodemographic Characteristics of the Sample

Characteristic	n	%[a]
Gender		
Female	83	100
Ethnicity		
Caucasian	72	88
African American	6	7
Other minorities	4	5
Marital status		
Married	61	75
Single	11	13
Divorced	10	12
Education completed		
High school	16	19
Some college	23	28
College graduate	26	32
Graduate degree	17	21
Religion		
Catholic	19	24
Protestant	41	51
Jewish	6	7
Other	11	14
None	3	4
Patient lives with		
Spouse	59	73
Other	9	11
Self	13	16
Average yearly income		
< $50,000	24	32
≥ $50,000	50	68
Occupation		
Professional	45	62
Nonprofessional	28	38
Work status		
Employed	58	73
Unemployed	22	27
Age (years)		
$\overline{X}$ = 44.47	–	–
SD = 7.29	–	–
Range = 22–59	–	–

[a] Some patients chose not to answer all questions. Missing data excluded for percentage computation where applicable.

N = 83

Table 2. Mean Pain Intensity Ratings During the Pre-Autotransplantation Period

Pain Intensity	$\bar{x}$	SD	Median	Range
Affective	3.45	4.14	2.5	1–24
Sensory	4.47	3.67	4.0	1–20
Total	6.92	6.86	6.0	1–44

Note. Fifty-four percent of the subjects experienced no pain.

N = 83

physical and role functioning, mental health, and health perceptions. Statistically significant ($p < 0.01$) correlations were found among all health measures. Cronbach's alpha, estimated for the four multi-item scales, ranged from 0.81–0.88 (Stewart et al., 1988).

Procedure

The Institutional Review Board approved the study prior to participant accrual. All participants were recruited by either the physician co-investigator or the BMT clinical nurse specialist co-investigator during a regularly scheduled pre-autotransplantation medical oncology outpatient clinic visit. All participants had been accepted into the autotransplantation program prior to receiving an invitation to participate in this study. Each participant signed an informed consent.

The subjects completed the questionnaires in a quiet, comfortable room located in the outpatient clinic. The BMT clinical nurse specialist provided the baseline questionnaires, clarified directions for completion, and retrieved the questionnaires from the participants. Subjects took approximately one hour to complete the questionnaires.

Data Analysis

Measures of central tendency were used to describe the sample and responses to the instruments. Correlations among pain intensity, psychological distress, catastrophizing, coping variables, and perceived health status were examined using Pearson product moment and Spearman's Rho correlations, as appropriate. Hierarchical multiple linear regression techniques were used to determine the best

Table 3. Locations of Pain Complaints During Pre-Autotransplantation Period

Pain Location	n	%
Vagina	16	19
Chest	12	14
Shoulder	11	13
Arm	8	10
Neck	5	6
Abdomen	4	5
Generalized	4	5
Breast	3	4
Joint/hand	3	4
Other	3	4
Mouth	2	2
Head (ache)	2	2
Rectum	1	1

N = 83

Table 4. Sensory and Affective Words Chosen to Describe the Quality of Pain During Pre-Autotransplantation Period

Words	n	%
Sensory		
Aching	21	25
Sore	20	24
Dull	11	13
Hurting	6	7
Burning	5	6
Shooting	4	5
Tearing	3	4
Stabbing	2	2
Radiating	2	2
Sharp	2	2
Cramping	2	2
Crushing	1	1
Pressing	1	1
Affective		
Annoying	22	26
Tiring	14	17
Troublesome	8	10
Nagging	8	10
Agonizing	3	4
Terrifying	2	2
Miserable	2	2
Torturing	1	1
Unbearable	1	1
Killing	1	1

N = 83

fit model that explained the maximum variance of total health status within the context of the study. Covariates in the model included age, pain, psychological distress (anxiety and depression), and coping (ability to control pain, use of positive coping statements, and catastrophizing).

Results

Sample Characteristics

The convenience sample of 83 female patients with breast cancer who were scheduled for autotransplantation was comprised primarily of Caucasian women who were well-educated, married, and employed in professional occupations with an average yearly household income of

Table 5. Mean Coping Strategies Questionnaire (CSQ) Ratings During Pre-Autotransplantation Period

Items on CSQ	$\bar{x}$	SD	Range
Ignoring pain	14.26	7.37	1–34
Coping statements	22.15	6.19	7–36
Reinterpreting pain	6.79	6.81	0–27
Diverting attention	17.08	7.66	1–34
Praying and hoping	19.31	8.23	2–35
Catastrophizing	6.22	5.87	0–26
Behavioral activity	17.36	5.73	3–31
Ability to control pain	3.99	1.11	1–6
Ability to decrease pain	3.80	1.29	1–6

N = 83

Table 6. Correlation Between Pain and Selected Variables

Variable	Pain (Overall Intensity)	Pain (Sensory)	Pain (Affective)	Anxiety (State)	Depression	Catastrophizing	Coping	Health Status (Total)	Physical Functioning	Role Functioning	Social Functioning	Mental Health	Health Perception	Pain
Pain (Overall Intensity)	1	–	–	–	–	–	–	–	–	–	–	–	–	–
Pain (Sensory)	0.67***	1	–	–	–	–	–	–	–	–	–	–	–	–
Pain (Affective)	0.71***	-0.04	1	–	–	–	–	–	–	–	–	–	–	–
Anxiety (State)	-0.07	0.03	-0.13	1	–	–	–	–	–	–	–	–	–	–
Depression	0.02	0.17	-0.12	0.61***	1	–	–	–	–	–	–	–	–	–
Catastrophizing	0.08	0.22	-0.09	0.29**	0.29**	1	–	–	–	–	–	–	–	–
Coping	0.16	-0.006	0.22*	-0.22*	-0.19	-0.20	1	–	–	–	–	–	–	–
Health Status (Total)	-0.20	-0.33**	0.004	-0.56**	-0.73***	-0.43***	0.12	1	–	–	–	–	–	–
• Physical Functioning	-0.16	-0.24*	-0.0005	-0.12	-0.22*	-0.23*	0.10	0.44***	1	–	–	–	–	–
• Role Functioning	0.03	-0.19	0.21*	-0.18	-0.33**	-0.21	0.23	0.50***	0.65***	1	–	–	–	–
• Social Functioning	-0.15	-0.33**	0.11	-0.33**	-0.57***	-0.30**	0.17	0.73***	0.42***	0.47***	1	–	–	–
• Mental Health	-0.05	-0.16	0.08	-0.66***	-0.71***	-0.27*	0.13	0.76***	0.04	0.17	0.44***	1	–	–
• Health Perception	-0.23*	-0.27*	-0.06	-0.41***	-0.54***	-0.39***	0.04	0.85***	0.23*	0.30**	0.49***	0.49***	1	–
• Pain	-0.16	-0.28**	0.04	-0.09	-0.32**	-0.39***	0.02	0.57***	0.40***	0.37***	0.59***	0.20	0.41***	1

*p < 0.05, **p < 0.01, ***p < 0.001

N = 83

more than $50,000. Data regarding the date of mastectomy and adjuvant chemotherapy were not obtained. Table 1 presents the demographic characteristics of the sample.

Pain

Fifty-four percent of the participants experienced no pain. All mean pain intensity scores were low (see Table 2). Although the mean pain scores were low for sensory, affective, overall intensity, and the Painometer-VAS, the range of reported scores was wide. This indicated that some subjects did experience moderate pain intensity.

Study participants experienced pain primarily in the vagina (19%), chest (14%), shoulder (13%), and arm (10%) (see Table 3). The words most frequently chosen to describe the sensory quality of pain were aching (25%), sore (24%), and dull (13%), and the words most frequently chosen to describe the affective quality of pain were annoying (26%), tiring (17%), nagging (10%), and troublesome (10%) (see Table 4).

Psychological Distress

The participants reported a range of mild (49%) to severe/high (26%) state anxiety ($\overline{X}$ = 41.43, SD = 12.67, range = 20–67). Forty percent of the sample experienced no depression, with a range of mild (36%) to severe/high (7%) depression reported ($\overline{X}$ = 11.66, SD = 7.73, range = 0–37).

Cognitive Coping Strategies

The subjects used a variety of coping strategies to deal with pain (see Table 5). Positive coping strategies (e.g., coping statements, praying and hoping, diverting attention) were used frequently. Catastrophizing, a negative coping strategy, was used less frequently. Overall, the results demonstrated that participants experienced a moderate ability to control and decrease pain.

Health Status

Subjects reported a mean total perceived health status rating of 50.30 (SD = 10.67, range = 18–72) of a possible total rating range of 0–91. A high mean rating was reported for mental health ($\overline{X}$ = 22.10, SD = 4.5, range = 8–29). A moderate mean rating was reported for pain ($\overline{X}$ = 4.11, SD = 1.28, range = 1–6), social function ($\overline{X}$ = 4.73, SD = 1.44, range = 1–6), and health perception ($\overline{X}$ = 14.66, SD = 4.98, range = 5–25). The lowest mean was reported for role functioning ($\overline{X}$ = 0.79, SD = 0.87, range = 0–2).

Correlations Among Selected Variables and Predictors of Health Status

Table 6 presents the correlations among pain, anxiety, depression, catastrophizing, coping, and health status. Significant correlations were observed between state anxiety and depression (0.61, p < 0.001) and physical functioning and role functioning (0.65, p < 0.001). Significant, negative correlations were seen between state anxiety and mental health (r = –0.66, p < 0.001), depression and total health status (r = –0.73, p < 0.001), and depression and mental health (r = –0.71, p < 0.001).

The variables of interest (pain, anxiety, depression, ability to control pain, and catastrophizing) all were significantly correlated to total health status. Bivariate correlation coefficients of these variables with total health status ranged from r = 0.33 (pain, p < 0.01) to r = 0.73 (depression, p < 0.001). Regression results from the model explained an overall variance of 65% (R^2 = 0.65, F = 22.48; p < 0.05) of the total health status based on the covariates in the chosen model. Statistically significant variables were sensory pain (β = –3.36, p < 0.05), depression (β = 0.73, p < 0.001), and catastrophizing (β = 0.36, p < 0.05).

Discussion

The sample characteristics describe a demographically homogeneous group of patients with breast cancer who were representative of patients awaiting autotransplantation at this comprehensive cancer center. The low-grade pain intensity and pain locations chosen (e.g., chest, shoulder, arm) and the pain descriptors (e.g., dull, sore, aching) may be related to numerous factors: previous breast cancer surgery (lumpectomy or mastectomy), a previously placed or removed central venous catheter used for the prior chemotherapy, or insufficient rehabilitation of the affected areas. Interestingly, note that this sample of patients experienced pain before any invasive procedures related to the scheduled autotransplantation (e.g., central line placement, bone marrow aspiration) were performed. The vaginal pain experienced also is interesting. This may be related to chemotherapy-induced mucositis or atrophic vaginitis. The continuous nature of low intensity pain can be very tiring and debilitating for patients.

Psychological distress was evident through the reporting of mild to severe depression and state anxiety. This fact demonstrates the necessity of screening for anxiety and depression in this population before admission for the autotransplantation. The majority of subjects chose positive coping strategies to cope with pain. However, the use of catastrophizing was present. Preadmission data are important as potential prognosticators of long-term QOL (Gaston-Johansson & Foxall, 1996) and future neurobehavioral disorders (Meyers et al., 1994). Assessing patients' anxiety, depression, and use of catastrophizing during the preadmission period is also of paramount importance to provide appropriate interventions because patients undergoing autotransplantation must adhere to the strict treatment protocol schedule.

Subjects reported a moderate total perceived health status. However, the range of scores was very wide, with some subjects reporting very low total health status scores. The low mean rating for role functioning may be related to a decrease in functional status (Cella & Tulsky, 1993). The significant, negative correlations between state anxiety and mental health, depression and total health status, and depression and mental health and the significant, positive correlation between state anxiety and depression demonstrate the importance of timely assessment and treatment of psychological distress. In addition, the variances in total health status explained by pain, state anxiety, and depression are important in this matter. The low role functioning has been reported previously. This role functioning may become very important to patients' ability to cope with the physiologic and psychological challenges engendered by the autotransplantation treatment process.

Implications

Nursing Practice

Patients with breast cancer who are scheduled for autotransplantation may experience pain, psychological distress, and alterations in coping during the prehospitalization period. These patients may experience difficulty in coping not only with the breast cancer diagnosis but also with recent surgical treatment and the anticipatory anxiety regarding the future scheduled intensive chemotherapy and autotransplantation process. Oncology nurses need to be cognizant of these potential complex psychological and physiologic challenges to make appropriate assessments, perform effective nursing care, and make necessary referrals. The fast-paced ambulatory care environment in which many patients are seen pretransplant necessitates that oncology nurses perform very focused patient assessments. Nursing assessments for anxiety, depression, and alteration in health status (specifically physical and role functioning) and coping should be a routine part of this pretransplant patient assessment. The economically driven trend toward earlier discharge for the BMT population in the United States makes this early assessment critical. Also, some BMTs now are performed in a modified outpatient setting. Many patients undergoing autotransplantation currently are expected to achieve effective self-care skills during a stressful time period.

Nursing Research

Nursing research is needed regarding interventions that use findings from this and other relevant research targeted at the specific needs of patients with breast cancer prior to autotransplantation concerning their pain, psychological distress, and alterations in coping and health status. Cognitive restructuring to change perception of pain and psychological distress and decrease the use of catastrophizing may be a useful component of these interventions. Nursing research also is needed regarding the etiology of pain in the population with breast cancer after treatment and prior to autotransplantation. The findings presented here regarding vaginal pain in patients with breast cancer are of research interest within numerous contexts, including vaginal mucosal response to varying chemotherapeutic protocols.

Recruitment of increased numbers of minority patients with breast cancer into research focusing on the autotransplantation experience is needed. External reliability of the research findings is compromised when a homogeneous sample is used, as in this study is used. We currently are unable to state precisely why this underrepresentation of minorities and medically underserved populations exists nationwide in patients recruited for autotransplantation. One potential reason may be economic barriers related to the cost of autotransplantation. The total autotransplantation treatment cost may range from $80,000 to more than $150,000 as compared to the cost of conventional chemotherapy, which ranges from approximately $15,000–$40,000 (United States General Accounting Office, 1996). Lack of insurance coverage may be an economic barrier to autotransplantation. Other potential reasons for this underrepresentation are issues related to access to autotransplantation, education regarding the autotransplantation process, and late stage of disease at diagnosis. Clearly, we need to assess why these populations are underrepresented in this treatment modality as interventions are developed and tested.

Conclusion

Patients with breast cancer who are scheduled for autotransplantation experienced low-grade pain intensity, psychological distress, and alterations in health status and coping during the prehospitalization phase prior to autotransplantation. Healthcare providers need to be aware of these potential experiences in order to promote appropriate assessments, provide effective care, and make necessary referrals. Further research regarding appropriate interventions, such as rehabilitation and coping strategies, is needed to assist patients with the many challenges associated with autotransplantation.

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For more information on this topic, visit these Web sites:

Bone Marrow Transplantation and High-Dose Chemotherapy: A Breast Cancer Study
http://www.tennode.org/

National Alliance of Breast Cancer Organizations
http://www.nabco.org/

National Breast Cancer Coalition
http://www.natlbcc.org/

These Web site are provided for information only. Hosts are responsible for their own content and availability. Links can be found using ONS Online at www.ons.org.

Appendix 5

The Effectiveness of the Comprehensive Coping Strategy Program on Clinical Outcomes in Breast Cancer Autologous Bone Marrow Transplantation
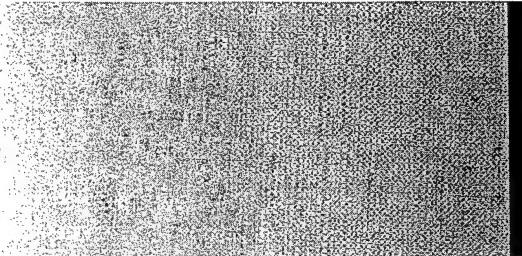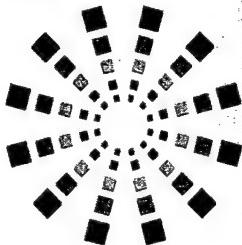
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The Effectiveness of the Comprehensive Coping Strategy Program on Clinical Outcomes in Breast Cancer Autologous Bone Marrow Transplantation

KEY WORDS

ABMT

Breast cancer

Coping

Fatigue

Multimodal intervention

Nausea

Pain

Psychological distress

Patients with breast cancer who undergo autologous bone marrow/peripheral blood stem cell transplantation (ABMT) cope not only with a life-threatening medical treatment, but also with multiple, interrelated symptoms including pain, fatigue, psychological distress, and nausea. The purpose of this study was to determine, in a randomized controlled clinical trial, whether a comprehensive coping strategy program (CCSP) was effective in significantly reducing pain, fatigue, psychological distress, and nausea in patients with breast cancer who underwent ABMT. The CCSP was composed of preparatory information, cognitive restructuring, and relaxation with guided imagery. Randomization placed 52 patients in the CCSP treatment group and 58 patients in the control group. The CCSP was found to be effective in significantly reducing nausea as well as nausea combined with fatigue 7 days after the ABMT when the side effects of treatment were most severe. These results are important given the high incidence of nausea and fatigue in the ABMT population. The CCSP-treated group experienced mild anxiety as compared with the control group who reported moderate anxiety. The greatest effectiveness of CCSP may correspond to the time of the greatest morbidity for patients with breast cancer who have undergone ABM.

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Accepted for publication February 23, 2000.

Autotologous bone marrow transplantation (ABMT) for breast cancer exploits the steep dose–response relation through the use of high-dose chemotherapy followed by rescue with either bone marrow or peripjheral blood stem cell transplantation to prolong survival and disease-free survival (1). Patients with breast cancer who undergo this treatment must cope not only with a' life-threatening medical treatment, but also with multiple, interrelated symptoms including pain, fatigue, psychological distress, and nausea (2,3). Compounding these stressors is the fact that patients often attempt to cope with the treatment and symptom experience in a geographically distant, unfamiliar medical center. The purpose of this study was to determine, in a randomized controlled clinical trial, whether a comprehensive coping strategy program (CCSP) was effective in significantly reducing pain, fatigue, psychological distress, and nausea in patients with breast cancer who underwent an ABMT.

■ Literature Review

Pain

Pain is a well-documented side effect of ABMT related to the high-dose chemotherapy regimen and/or procedures related to ABMT (2,3). High-dose chemotherapy may lead to painful oral ulcerations, chemical cystitis, and nausea and vomiting (2). Numerous invasive techniques such as bone marrow aspirations, lumbar punctures, and central catheter placement also may cause pain (4). Pain also may be present before the ABMT. In a predictive, correlational study using 127 women with stage II, III, or IV breast cancer, 47% of the participants reported pain at baseline approximately 35 days before ABMT (5).

Pain associated with ABMT may not be the result of nociceptive processes entirely. Hill et al. (6) found that morphine administered over a 9-day period to patients who underwent ABMT reduced pain only to approximately 50 on a 100-point visual analog scale (VAS). Pain treated with intravenous morphine and/or demerol still persisted for about 3 to 4 weeks (6). These limited effects of morphine and demerol were verified by Gaston-Johansson et al. (3), who reported that the pain experienced by patients who underwent ABMT reached its peak 5 days after ABMT, was rated as mild to moderate, lasted 15 to 20 days, and was generalized throughout the body (3).

The multidimensionality of pain is demonstrated by the reports of patients with cancer pain who experience more depression, fatigue, and symptom distress as well as lower interpersonal well-being than pain-free patients (3,7,8). Pain frequency has been found to correlate significantly with fatigue and depression (9). Pain often is used as a metaphor for advancing disease and death by both patients and family members (9).

Many patients have reported using cognitive–behavioral strategies including hypnosis, relaxation with guided imagery, distraction, and support groups in an attempt to reduce discomfort (10). A pilot study by Arathuzik (11) found that teaching relaxation, visualization, and cognitive coping skills in busy clinical settings to both inpatients and outpatients with breast cancer was effective in relieving some pain. These cognitive–behavioral approaches have proven effective in relieving pain in patients with breast or lung cancer, but need to be evaluated in clinical trials (11–13). Regardless of the type of pain relief intervention used, for pain relief to occur, it is important to remember that patients need to cope with the psychological distress arising from their cancer diagnosis and cancer treatment experience.

Fatigue

Fatigue is the most commonly reported symptom associated with cancer, and also the most commonly reported side effect of chemotherapy, with up to 99% of patients reporting this symptom (14,15). Approximately 33% to 76% of patients who undergo ABMT experience a high degree of fatigue (16), which has been found most severe 5 days after ABMT (3). Fatigue also may precede the ABMT. Gaston-Johansson et al. (5). found that 91% of patients (n = 127) with breast cancer awaiting ABMT reported fatigue at baseline approximately 35 days before ABMT.

Numerous treatment and disease-related factors contribute to fatigue including surgery, chemotherapy, radiation therapy, interferons, immunosuppression, infections, anorexia, weight loss, psychological distress, chronic pain, and alterations in sleep patterns (17,18). Chemotherapy-related cell destruction end products, nausea, and vomiting also are thought to be contributing factors (19).

Fatigue and its affects on mood, concentration, and activities of daily living have been investigated primarily as they relate to chemotherapy and radiation therapy. Few studies have examined the fatigue experience longitudinally from one treatment method up to and through preparation for another treatment method. Fatigue also may lead to decreased patient QOL (20). Irvine, Vincent, Bubela, Thompson, and Graydon (14) found that as fatigue increased, so did symptom distress, mood disturbance, and loss of ability to perform usual physical, recreational, vocational, home, and social activities. These lifestyle alterations may cause the patient to experience anxiety and depression.

Fatigue also was found not to correlate significantly with duration of disease status or with stage of disease. Furthermore, fatigue has been linked with impairment of cognitive functioning and impaired perception and thinking ability (21). Graydon et al. (22) found that patients undergoing chemotherapy who were able to use effective fatigue-relieving strategies reported less fatigue than patients who used less effective strategies such as eating, drinking, or watching television. Clearly, managing fatigue is a great challenge for oncology nurse researchers and clinicians (21).

Anxiety and Depression

Patients undergoing ABMT have reported moderate anxiety and depression during hospitalization, with anxiety and

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depression reaching peak intensity 5 days after ABMT (3) and at discharge. Among patients undergoing ABMT, 40% were found to have major depression at some stage during the ABMT procedure (23). As many as 71% of women treated with chemotherapy for breast cancer reported psychological distress, including anxiety and depression at the end of treatment.

Case studies and anecdotal description suggest that strict isolation, medical procedures, and pain are frequent contributors to anxiety and depression in patients undergoing ABMT, with pain described as the most frequent factor (19,23). Psychological distress also may precede the ABMT. Gaston-Johansson et al. (24) found that 60% of the patients with breast cancer (n = 83) awaiting ABMT reported depression approximately 35 days before ABMT.

Research documenting a positive relation of pain to anxiety and depression in patients with cancer is extensive (3,8). Massie (25) found from analyzing 20 years of research regarding depression in patients with cancer that approximately 25% were depressed, and that up to 50% exhibited some symptoms of depression. The importance of adhering to a strict schedule of treatment to halt the spread of cancer has been well documented. Therefore, addressing patients' anxiety and depression over the course of treatment is of paramount importance.

Elevated levels of depression and anxiety may persist in a minority of patients with breast cancer even years after the diagnosis (26). Patients reported diminished anxiety toward the end of chemotherapy, but they continued to have specific anxieties regarding the termination of the close medical supervision and the possibility of cancer recurrence (27,28).

Nausea

Nausea is a common symptom associated with chemotherapy treatment (29). The literature shows several main responses associated with the impact of nausea in patients with cancer including anxiety, depression, autonomic nervous system responses, social withdrawal, and food aversion (30,31).

The experience of nausea usually is accompanied by increased salivation, swallowing, and tachycardia (32). Many studies have found that nausea is a significant independent indicator of QOL on the first day and a few days after administration of chemotherapy (33).

Pharmacologic and cognitive–behavioral interventions have been used successfully to manage nausea. Cognitive–behavioral interventions include distraction, progressive muscle relaxation, guided imagery, biofeedback, and hypnosis (28,34,35). The most effective treatment strategy for managing nausea combines these approaches because no strategy is totally effective when used alone (32).

In summary, the complex interrelatedness of pain, fatigue, psychological distress, and nausea experienced by patients with breast cancer undergoing ABMT makes symptom management a challenge for clinicians. A need exists for individualized nursing interventions targeted at reducing the side effects of treatment for breast cancer (36).

■ Theoretical Support for the Comprehensive Coping Strategy Program

The gate-control theory of pain by Melzack and Wall (37) and the stress, coping, and adaptation paradigm by Lazarus (38–40) provide the theoretical framework for use of the CCSP. Pain is defined as a multidimensional sensory and affective experience associated with discomfort (41). According to the gate-control theory, the central system located in the brain can be stimulated by cognitive processes, past experiences, anticipation and attention, and anxiety to open or close the gating mechanism permitting or preventing the transmission of nociceptive impulses to the brain (37).

Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and/or internal demands appraised as taxing or exceeding the resources of a person (38). Positive coping strategies refer to internal thoughts and behaviors that people use to manage their pain or their emotional reactions to the pain, and to reduce emotional distress. *Catastrophizing,* a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future (42). Negative thoughts have been associated with negative health outcomes.

The purposes of the CCSP are the following: (a) to give the patient preparatory information, both objective and subjective, regarding potential side effects of ABMT; (b) to enhance the coping ability of the patient by teaching her to recognize and avoid distorted thinking and catastrophizing, and to use positive coping self-statements; and (c) to teach the patient how to use relaxation with guided imagery. The following individual components of the CCSP have been proved effective in reducing pain and emotional distress: (a) preparatory information to increase control (43); (b) cognitive restructuring, which includes positive coping statements and avoidance of catastrophizing (43,44); and (c) relaxation with guided imagery (45–47).

Cognitive–behavioral strategies are used frequently to help control a wide range of symptoms such as pain, fatigue, anxiety, depression, and nausea (34,48). The components of the CCSP are thought to reduce pain by closing the gating mechanism through their effect on the central control system (37). Jensen, Turner, Romano, and Karoly (48) reviewed empirical research related to the relations among beliefs, coping, and adjustment to pain. They found that patients who believe in their ability to control pain, who avoid catastrophizing, and who do not view themselves as severely disabled appear to function better than those who do not. They recommended increased use of experimental research designs to examine critically the causal relations among beliefs, coping, and adjustment to pain.

Cognitive–behavioral training helps to develop coping skills and lessens the anxiety and depression, which may exacerbate the symptom (49). The efficacy of relaxation and psychological counseling is well established (49). Progressive muscle relaxation and imagery (46) have been found to help patients either to escape the problem or to think of the problem in alternative ways. Incorporation of relaxation techniques into the CCSP may allow for further emotional relief in alleviating a patient's fatigue.

Symptomatology related to high-dose chemotherapy and ABMT can be distressing over time. Therefore, it is important to teach the patient the CCSP before treatment, and to reinforce the CCSP regularly during the course of treatment (47). Patients with breast cancer undergoing ABMT are appropriate candidates for preparatory information because the treatment side effects are both short and long term, and the preparatory information is targeted to their increased use of positive coping strategies. The previous research and preliminary studies of Gaston-Johansson et al. (3,24) support the use of the CCSP. The mechanisms of action associated with behavioral therapies and the attenuation of pain as well as how people cope with the ABMT process require further elucidation (50).

No prospective or retrospective study was found in the scientific literature that included the three components of the CCSP in a unified coping strategy program to reduce pain, emotional distress, and fatigue in patients with breast cancer undergoing ABMT. Therefore, this is the first study to examine the effectiveness of the CCSP in this population.

Hypothesis

Patients with breast cancer who undergo ABMT and receive a CCSP report significantly less pain, fatigue, psychological distress, and nausea than patients undergoing ABMT who do not receive a CCSP.

■ Methods

Design

This study used an experimental design using random assignment of patients with breast cancer to one of two possible groups. Thus, it was a randomized, controlled, prospective clinical trial. Participants were randomized to one of the following two groups: group I: patients with breast cancer scheduled for ABMT who received the CCSP (treatment group) or group II: patients with breast cancer scheduled for ABMT who did not receive the CCSP (control group). Both groups received usual medical treatment and nursing care.

The study was approved by the Institutional Review Board before participant accrual. All participants were recruited by either the physician or the bone marrow transplantation (BMT) clinical nurse specialist coinvestigator during a regularly scheduled pre-ABMT medical oncology outpatient clinic visit. All participants had been accepted into the ABMT program before being approached. Written informed consent was obtained, and baseline data were collected before the participants were randomly assigned to a group.

Sample and Setting

A consecutive sample of 128 women with stage II, stage III, or stage IV breast cancer who were scheduled for ABMT at an urban National Cancer Institute–designated comprehensive

cancer center located in the eastern United States agreed to participate in the study. Eligibility criteria for the participants required a diagnosis of stage II, III, or IV breast cancer; a scheduled ABMT; age of 18 years or older; and ability to read and write English. It was found that 18 subjects did not meet this criteria (3 subjects had their ABMT canceled, 10 refused to participate after they had signed consent forms, and 5 were too ill to participate in the CCSP). The final sample comprised 110 participants.

Procedure

The participants completed the baseline questionnaires in a quiet, comfortable room located in the outpatient clinic. Patients were told that they could take a break at any time during data collection. The BMT clinical nurse specialist provided the baseline questionnaires, answered the participants' questions, and retrieved the questionnaires after completion. It took approximately 1 hour for the participants to complete the questionnaires.

The participants completed the questionnaires 2 days before ABMT and 7 days after ABMT in their hospital rooms. The CCSP was reinforced on the same day the patient was admitted to hospital, 2 days after completion of chemotherapy, and 7 to 9 days after the ABMT. An experienced ABMT oncology nurse, the principal investigator, or the project director provided the reinforcement.

■ CCSP Intervention

The CCSP was taught to patients in the treatment group by a clinical social worker at least 2 weeks before hospital admission for treatment with high-dose chemotherapy and ABMT. Preparatory information was presented, which stressed that adequate control of pain can lead to decreased psychological distress and a decrease in physical symptoms such as fatigue. Handouts were given to each participant regarding ways to reduce pain and psychological distress and general ways to increase control. Theoretical considerations regarding treatment of pain were presented including definition of pain, three components of pain, a brief explanation of the gate control theory, and theoretical reasons why increasing control through the use of the coping self-statements and relaxation with guided imagery can decrease pain and emotional distress. A handout explaining ways to help reduce pain was given to each participant. Cognitive restructuring information focused on the avoidance of catastrophizing, distorted thinking, and the use of positive coping self-statements. Two handouts were used that explained styles of distorted thinking to avoid and 15 positive coping self-statements to use.

Relaxation with guided imagery was presented via live model in a participant-modeling format by the social worker. Participants were taught how to do a brief muscle relaxation procedure and cue-controlled relaxation with the word "relax." Imagery was introduced into the relaxation exercise. At the

completion of the session, two handouts were given to the participants that presented the way to use relaxation therapy and explained its benefits.

A small handheld audiotape recorder with earphones and an audiotape was given to each participant. The purpose of this tape was to guide the participants through active participation in the relaxation exercise. Participants were instructed to use the 5-minute audiotape at least every day and before stressful events. They also were instructed in reviewing the handouts and recording their use of the audiotape and handouts in a diary.

Instrumentation

SOCIODEMOGRAPHIC VARIABLES

The Sociodemographic Questionnaire included the following items: age, gender, race/ethnicity, marital status, education level, religion, patient living arrangements, average yearly household income, occupation, work status, household income, type of chemotherapy, breast cancer stage; and the participants' previous use of relaxation and coping strategies.

PAIN

Pain was measured with the Gaston-Johansson Painometer (POM)®, which was designed to assess the patients' overall pain intensity, the intensity of the sensory and affective components of pain, and the quality of pain (51). The POM is a hard, white plastic tool 8 inches long, 2 inches wide, and $\frac{1}{4}$ inch thick. It is lightweight and held easily by the subject. A list of 15 sensory and 11 affective pain word descriptors is located on the front side of the POM (POM-WDS), and a 100-mm VAS with a movable marker (POM-VAS) is located on the back side of the POM.

An intensity value (from a low of 1 to a high of 5) is predetermined for each sensory and affective word located on the POM-WDS. A maximum score of 36 can be obtained for the sensory component of pain, and a maximum score of 34 for the affective component. A total score can be obtained by adding the sensory and affective scores. An overall score of 1 to 10 also can be obtained for pain intensity on the POM-VAS. Test–retest reliability, concurrent validity, and construct validity have been demonstrated for the POM (51).

NAUSEA

The severity of nausea was measured using the nausea VAS, a 100-mm vertical line with "no nausea" at one end and "nausea as severe as can be" at the opposite end. The subject responds by placing a horizontal mark through the vertical line indicating the degree of nausea she currently is experiencing. When used properly, the VAS is a reliable, valid, and sensitive self-report tool for studying subjective symptoms (52).

FATIGUE

Fatigue was measured using the fatigue VAS, a 100-mm vertical VAS anchored with "completely exhausted" and "no fatigue" at opposite ends. The subject makes a horizontal mark through the vertical line indicating the degree of fatigue she currently is experiencing.

Reliability and validity of the fatigue VAS have been demonstrated through the VAS scales used on the Piper Fatigue Scale (53).

PSYCHOLOGICAL DISTRESS

Anxiety. The State-Trait Anxiety Inventory (STAI) (54) was used as one measure of psychological distress. The STAI consists of two separate self-report scales for measuring state and trait anxiety (54). *State anxiety* is a transitory emotional response to a stressful situation. *Trait anxiety* reflects a stable predisposition to anxiety as determined by a personality pattern. Respondents rate themselves in relation to the statement on a Likert scale from 1 to 4. The total score is the sum of all 20 responses and ranges from a minimum score of 20–39 (low anxiety) to 40–59 (moderate anxiety) to a maximum score of 60–80 (high anxiety). Scores are reported to be considerably higher under stress conditions than under normal conditions (54). Test–retest reliability and construct validity of the STAI has been demonstrated (54).

Depression. The Beck Depression Inventory (BDI) (55) was used to measure psychological distress. The BDI consists of 21 items that describe particular symptoms of depression (55). Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores range from 0–9 (normal) to 10–15 (mild depression) to 16–23 (moderate depression) to 24–63 (severe depression). The total score (range, 0–63) is obtained by summing the 21 responses. Test–retest correlations of the BDI ranged from 0.60 to 0.90 in nonpsychiatric patients (55).

■ Statistical Analysis

Preliminary analysis of the data included exploratory data analysis to ascertain data quality, to handle outliers and missing data, and to measure group differences among sociodemographic characteristics, disease stage, and types of chemotherapy. Descriptive statistics (frequency, percentage, mean, median, and standard deviation) were used to describe the sample and responses to the instruments.

The primary hypothesis concerning the between-group difference of the independent variable (exposure to the CCSP) and the difference between measurement points on each dependent variable over time was tested with multivariate analysis of covariance (MANOVA) (56). The independent variable and the multiwave repeated measures variables were evaluated within the same MANOVA design. Possible covariates in the analysis were baseline pain, psychological distress, and fatigue (PPF), intermediate PPF, medications, chemotherapy type, and relevant demographic characteristics. The statistical power of analysis to reject the null hypothesis of no intervention effect was estimated to be 80%, with an alpha of 0.05, a medium effect size, a sample size of 55 patients per group, and a one-tailed test (56).

■ Results

Sample Characteristics

Demographic characteristics of the sample are presented in Table 1. Most of the patients were 41 to 50 years old. As reported, 90% in the CCSP group were married as compared with 57% in the control group ($p < 0.001$). The CCSP group had a statistically significant lower annual household income ($p < 0.05$) than the control group. Findings showed that 40% of the participants in the CCSP group as compared with 21% in the control group had practiced some earlier coping methods ($p < 0.05$). There were no statistically significant differences between the groups with regard to stage of the disease and type of chemotherapy treatment.

Pain

Pain was reported by 47% of the participants. The sensory pain scores were slightly higher than the affective scores 7 days after the ABMT (Table 2). Total pain scores were lowest 2 days before ABMT for the treatment group. Pain scores increased gradually and reached their peak intensity 7 days after ABMT for both groups. There were no statistically significant differences between the groups with regard to the intensity of the different pain scores.

Table 1 • DEMOGRAPHIC CHARACTERISTICS OF THE SAMPLE (N = 110) (%)

Attributes	CCSP[a] n = 52 (%)	Control n = 58 (%)
Age		
22–40 years	11 (21.2)	17 (29.8)
41–50 years	26 (50.0)	32 (56.2)
51 years and older	15 (28.8)	8 (14.0)
Race: white	46 (88.5)	48 (82.8)
Employment status: employed	38 (73.1)	36 (62.1)
Marital status: married	47 (90.4)	33 (56.9)
Education		
High school	8 (15.4)	10 (17.5)
Some college	10 (19.2)	18 (31.6)
College/graduate degree	34 (65.4)	29 (50.9)
Occupation: professional	34 (65.4)	32 (55.2)
Income: Less than $50,000/year	10 (19.2)	22 (37.9)
Cancer stage		
II 13 (22.4%)	8 (15.4)	
III 17 (29.3%)	32 (61.5)	
IV 28 (48.3%)	12 (23.4)	
Chemotherapy type		
I[b]	22 (42.3)	30 (56.9)
II[c]	30 (57.7)	25 (43.1)
Prior coping methods	21 (40.4)	12 (20.7)*
Prior relaxation methods	20 (38.5)	18 (31.0)

[a]Comprehensive coping strategy program.
[b]Cytoxan, thiotepa.
[c]Cytoxan, thiotepa, carboplatin.
[d]$p < 0.001$; *$p < 0.05$.

The most frequent words chosen by the participants to describe the sensory component of pain were aching (25%), sore (24%), and dull (13%). The most frequent affective words were annoying (26%), tiring (17%), troublesome (10%), and nagging (10%). The pain was most frequently located in the vagina (19%), chest (14%), shoulder (13%), and arm (10%). Only two participants reported pain in the mouth or throat.

Nausea

Nausea was reported by 55% of the participants. In the CCSP group, nausea was more severe 2 days before ABMT than 7 days after ABMT. The opposite was observed in the control group, with nausea reaching its greatest intensity level 7 days after ABMT. Nausea was 23 points higher in the control group than in the CCSP group 7 days after ABMT. There was a statistically significant difference between the groups regarding nausea on day 7, with the CCSP treated group reporting less nausea than the control group ($F[1,72] = 5.50$; $p < 0.05$). After control for demographic variables, other relevant covariates, and the nausea score 2 days before ABMT, there still was a group difference 7 days after ABMT, with the CCSP group showing significantly lower scores statistically than the control group ($B = -16.94$; $\beta = -0.28$; $p < 0.05$).

Fatigue

Fatigue was experienced by 91% of the participants. The fatigue reached its peak 2 days before ABMT for both groups, increasing by 10.80 points in the CCSP group as compared with 20.33 points in the control group. On day 7 after ABMT, the control group rated their fatigue as 9.44 points higher than the CCSP group. There were no significant differences statistically in fatigue levels between the groups 2 days before ABMT. There was, however, a significant difference between the groups 7 days after ABMT, with the CCSP group experiencing less fatigue ($F[1, 63] = 4.01$; $p < 0.05$). This difference disappeared after control for demographic variables and fatigue 2 days before ABMT. When an index of nausea and fatigue was created for day 7 after ABMT, with demographic variables controlled, there was a statistically significant difference between the groups, with the control group reporting nausea and fatigue ($B = -26.23$; $\beta = -.27$; $p < 0.05$).

Psychological Distress

Depression was reported by 54% of the participants reported depression and anxiety by 100%. Anxiety remained constant for the control group from baseline to day 7 after ABMT day, but had decreased by 9 points in the CCSP group from baseline by day 7 after ABMT. Depression increased in both groups over time, reaching its peak level in the control group on 2 days before ABMT. Anxiety was 10 points higher in the control group (moderate anxiety) than in the CCSP group (mild anxiety) on day 7 after ABMT. There were, however, no statistically significant differences between the groups with regard to psychological distress.

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	Table 2 • SYMPTOMS EXPERIENCED AT BASELINE 2 DAYS BEFORE (DAY −2) AND 7 DAYS AFTER (DAY +7) AUTOLOGOUS BONE MARROW TRANSPLANTATION (N = 110)						
		Baseline		Day −2		Day +7	
Symptom	Group	Mean	SD	Mean	SD	Mean	SD
Pain							
Affective	Tx	1.38	3.72	1.66	3.49	2.70	5.75
	C	2.05	4.41	2.67	5.58	2.45	4.54
Sensory	Tx	2.12	4.48	1.10	2.03	4.46	5.50
	C	2.63	3.41	2.18	3.81	3.36	5.18
Total	Tx	3.50	7.66	2.76	4.69	7.16	8.45
	C	4.68	7.11	4.84	8.22	5.82	9.32
VAS	Tx	5.89	13.08	14.50	15.36	29.50	28.23
	C	6.07	11.42	11.62	7.89	19.86	24.17
Fatigue	Tx	31.35	26.00	42.15	26.63	40.92	27.36
	C	31.35	28.23	51.68	28.64	50.36	27.25
Nausea	Tx	3.94	10.63	27.60	27.92	19.65	25.16
	C	5.80	16.86	25.74	28.09	32.20	32.51
Anxiety	Tx	40.16	12.15	39.50	10.41	30.65	11.53
	C	40.93	12.42	41.14	11.59	40.26	11.00
Depression	Tx	9.17	6.05	10.05	6.31	10.33	6.86
	C	11.44	7.88	13.56	11.50	12.25	8.01

Tx, ; C, ; VAS, Visual analog scale.

The Correlations Among Pain, Fatigue, Nausea, and Psychological Distress

As can be seen in Table 3, all symptoms (pain, fatigue, anxiety, depression, and nausea) were significantly correlated with each other. The highest correlations were noted between anxiety, depression, and nausea.

■ Discussion

The CCSP was found to be effective in significantly reducing nausea as well as fatigue combined with nausea when the side effects of treatment were most severe. These results are very important considering that nausea is a commonly experienced symptom associated with chemotherapy (29) and that up to 76% of patients who undergo ABMT experience a high degree of fatigue (16). The CCSP, by reducing nausea and fatigue, may also have an indirect effect in reducing other symptoms. Nausea has been associated with increased anxiety and depres-

	Table 3 • CORRELATIONS AMONG PAIN, FATIGUE, ANXIETY, DEPRESSION, AND NAUSEA TWO DAYS AFTER BONE MARROW TRANSPLANTATION			
	Pain	Fatigue	Anxiety	Depression
Fatigue	0.30[a]			
Anxiety	0.43[a]	0.43[a]		
Depression	0.32[b]	0.32[c]	0.59[a]	
Nausea	0.45[a]	0.51[a]	0.43[a]	0.23[d]

[a]$p < 0.001$; [b]not significant; [c]$p < 0.01$; [d]$p < 0.05$.

sion as well as tachycardia, which may have an impact on QOL (20,33). Fatigue also has been shown to have an effect on the QOL of patients with breast cancer. Fatigue has been associated with increased nausea and vomiting (19), anorexia, psychological distress, pain, and alterations in sleep patterns (16,17).

The results of this study support earlier findings in that pain reached its peak on 7 days after ABMT. Although a continuous low-grade pain was reported by most of the participants, it is important to remember that pain may cause great symptom distress to the patient over time, especially when the pain is continuous. The reported location of pain in the chest and shoulder may be related to manipulation of the nerves and muscles in the chest during mastectomy. Pain located in the vagina, found in an earlier study by Gaston-Johansson et al. (3), may be related to atrophic vaginitis. This vaginal pain may be amenable to management and should be explored further. Earlier studies have reported stomatitis as a major problem causing pain in patients treated with high-dose chemotherapy (2,3). It was therefore surprising to find that so few patients reported pain in the mouth and throat.

It is also interesting to note that 40% of the treatment group had used coping methods and 38% had used relaxation before taking part in this study. Participants were not asked to describe which coping and/or relaxation methods they had used previously. The current data, however, showed that previous use of these interventions had no significant effect on the outcomes of this study. Future research should include this data.

The current results showed that both groups of patients experienced mild depression after chemotherapy and ABMT. The CCSP-treated group experienced mild anxiety as com-

pared with that of the control group, which experienced moderate anxiety. Although these results were not statistically significant, they may be clinically significant. Increased anxiety has been associated with increased pain, depression, fatigue, and nausea, and decreased QOL. Conversely, mild anxiety may have some positive effects by motivating patients to use the CCSP when needed. The results of this study are very important because of the multiple symptoms experienced and the relation shown among these symptoms, which may make it difficult to reduce the suffering experienced by the patients. The multimodel nature of the CCSP may make capable of alleviating some side effects of cancer treatment.

The CCSP may have been effective because of its multimodal nature. Woods (57) noted that a nursing intervention often demonstrates no positive effects because the treatment is not sufficiently effective. To create an effective treatment, it is logical to test a multimodal intervention such as the one used in this study. Because the symptoms experienced with ABMT are multidimensional, logic suggests using a multimodal strategy to effect a change in these symptoms.

The CCSP was reinforced three times by project personnel during hospitalization using audiotapes and handouts, which was necessary for documenting a minimum use of the CCSP. The patients were given the audiotapes and handouts to take home, which made it possible for them to participate in the CCSP when they needed it before, during, and after hospitalization independently of the health care provider. Future studies should include the patients' independent use of the CCSP in statistical calculations to determine the appropriate "dose" of the CCSP.

The sample consisted primarily of a select group of highly educated, married, white women with high incomes. These demographics echo the paucity of ethnic diversity seen in the ABMT literature. Numerous barriers such as lack of transportation, inability to take necessary time away from the work site to complete the AT and the recovery period, lack of insurance coverage, and financial constraints may account for this lack of ethnic diversity. Targeted recruitment efforts are needed to offer the ABMT treatment, as clinically appropriate, to ethnically diverse patients with breast cancer. Limitations of this study included use of a single clinical site and a select sample of patients with breast cancer.

This is the first time that the effectiveness of the unique combination of preparatory information, cognitive restructuring, and relaxation with imagery has been tested in a randomized controlled clinical trial on patients with breast cancer undergoing ABMT. Postmastectomy patients with breast cancer undergoing ABMT are appropriate candidates for preparatory information because of the multiple symptoms associated with the side effects of treatment. Future studies should investigate the effectiveness of the CCSP in other diverse groups of patients with cancer who receive chemotherapy treatment.

■ Conclusions

In a randomized controlled clinical trial, a CCSP was effective in reducing nausea and fatigue significantly in patients with breast cancer who underwent high-dose chemotherapy and ABMT. The CCSP-treated group experienced mild anxiety as compared with the control group that reported moderate anxiety.

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Appendix 6

The Effects of a Comprehensive coping Strategy Program on Mortality

The Effects of a Comprehensive Coping Strategy Program on Mortality

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Word Count: 2,979

Abstract

Purpose: The purpose of this study was to determine if a Comprehensive Coping Strategy Program (CCSP) had an effect on mortality in breast cancer patients treated with autologous bone marrow transplant (ABMT).

Procedures: Total sample size was 110, with 52 patients randomized to the CCSP group. A RCT was used to compare mortality outcomes between the experimental CCSP group and control group who received usual care. The CCSP was taught to patients at baseline and reinforced periodically during hospitalization.

Findings: When stratified by group, 4 patients in the CCSP group (7.7%) compared to 12 in the control group (20.7%) had died at follow-up ($p < 0.05$). The odds ratio for mortality among the CCSP group was 0.32. CCSP patients were 9% less likely to die ($p < 0.05$) when adjustments were made for demographics, metastatic stage, type of chemo-therapy, and previous use of coping, relaxation methods, and follow-up period of 1 to 3 years.

Keywords: Comprehensive Coping, Mortality, Breast Cancer, ABMT, Chemotherapy, Stage of Disease, Demographics

INTRODUCTION

The purpose of this study was to determine if a Comprehensive Coping Strategy Treatment Program had an effect on mortality in breast cancer patients treated with ABMT. Breast cancer in the United States is estimated to be diagnosed in 175,000 new women in 1999, and 43,300 women are predicted to die from this disease[1]. Survival rates in breast cancer are correlated with the extent of disease[2]. This is evidenced by the ten year survival rate of 65% to 80% for women with disease confined to the breast compared to a median survival rate of approximately 2 years and a 2% to 5% probability of 5-year survival for women with metastatic disease[2]. The estimated number of deaths from breast cancer in the U.S. for 1998 is 16% of all types of cancer in women. Mastectomy followed by high dose chemotherapy and autologous bone marrow transplant (ABMT) is one treatment modality developed in response to the challenge of improving mortality and extending survival.

Autologous bone marrow transplant is a therapeutic modality which exploits the steep in-vitro dose response tumorcidal effect of chemotherapy in breast cancer followed by rescue with the reinfusion of either the patient's own cryopreserved bone marrow cells (BMT) or peripheral blood stem cells (PBSCT). More than 5,000 ABMT's are performed annually wordwide[3]. The use of ABMT for breast cancer comprised 15% of transplants in 1989, increasing to 35% in 1994[4]. Ten to thirty percent of breast cancer patients with chemotherapy-sensitive Stage IV breast cancer, may be alive and free from disease at two to five years following ABMT[5-7].

Although patients recognize that the ABMT may possibly save their lives, many patients may suffer to the extent that they regret having the treatment[8-9]. Bone marrow transplant has been associated with multiple symptoms such as pain, fatigue, nausea, psychological distress and alterations in coping[10-16]. Anticipatory anxiety may be generated by knowledge that ABMT can

lead to great physical and psychological distress including, but not limited to, the following: gastrointestinal complications - painful effects on the epithelial membranes of the oral cavity (mucositis, ulcerations), gastritis, diarrhea, nausea and vomiting; genitourinary complication - painful effects on the mucosal epithelial membranes of the bladder wall (chemical cystitis); veno-occlusive disease; infection; high fever and sepsis; hemorrhage; renal complications; neurological complications; cardiac toxicities; alopecia with resultant effects on body image and fatigue, psychological distress and death[17]. These multiple symptoms[18], accompanied by psychological distress, and fear of death can all be seen as physiologic and psychologic stressors that need a multimodal approach for successful treatment. Anderson and associates (1998) showed that physiologic effects of stress inhibited cellular immune responses that are relevant to cancer prognosis, including NK cell toxicity and T-cell responses[19]. Only one study was found where breast cancer patients with metastatic disease, who received a non-invasive psychosocial treatment, lived significantly longer than the patients who did not receive the treatment.[20]

HYPOTHESIS

Patients with breast cancer who undergo ABMT and receive a Comprehensive Coping Strategy Program (CCSP) are less likely to die than patients with breast cancer who undergo ABMT and do not receive the CCSP. The Comprehensive Coping Strategy Program (CCSP) is composed of preparatory information, cognitive restructuring and relaxation with imagery.

METHODS

Design and Ethics

This study was a randomized controlled prospective clinical trial. Using a computer-generated list, participants were randomly assigned to one of the following two groups after informed consent had been obtained and baseline data were collected, as approved by the

Institutional Review Board. Both groups received usual medical treatment and nursing care.

Group I: Patients scheduled for ABMT who received the CCSP (treatment group).

Group II: Patients scheduled for ABMT who would not receive the CCSP (control group) (Table 1).

The CCSP was taught to patients in the treatment group by a social worker with special education and experience in presenting the CCSP. This was done at least two weeks prior to patients being admitted to hospital, before treatment with high-dose chemotherapy and ABMT. The CCSP was reinforced on the same day the patient was admitted to the hospital, 2 days after completion of chemotherapy, and 7-9 days after the ABMT. Patients learned the CCSP so that they could use it as frequently as needed and independently of the health care provider. The reinforcement of the CCSP was performed by a registered nurse or the project director with CCSP training. The CCSP was standardized by the use of a written script, an audiotape and written handouts for reinforcement. The patients were given the audiotape and written handouts and instructed to use them as needed.

Patients and Setting

A consecutive sample of 127 women with Stage II, Stage III, or Stage IV breast cancer, who were scheduled for ABMT at an urban National Cancer Institute designated cancer center located in Eastern United States, agreed to participate in the study. The target accrual for this study based on a power analysis, was 54 subjects in each group. Once recruited, the following eligibility criteria were used for participation in the study: subjects in both groups underwent ABMT and those in the treatment group participated in the CCSP. Seventeen subjects did not meet these criteria (3 had their ABMT canceled, 10 subjects refused to participate in the study after they had signed consent forms, and 4 subjects were too ill to continue to participate in the CCSP). The final sample was 110 subjects.

Theoretical Considerations and Purpose of CCSP

Cognitive-behavioral interventions have been shown to be effective in reducing multiple symptoms including pain, anxiety, depression, and nausea in cancer patients[21]. The efficacy of relaxation, psychological counseling, and coping have been well established[21]. The stress associated with multiple symptoms can affect the immune system, possibly reducing the ability of individuals with cancer to resist disease progression and metastatic spread[19]. Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources of a person[22]. Positive coping strategies refer to internal thoughts and behaviors people use to manage undesirable symptoms, their pain, or their emotional reactions to the pain and to reduce emotional distress[22]. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future[22].

The purposes of the CCSP are to (a) give the patient concrete objective information about what may be expected regarding side effects of chemotherapy and ABMT treatment in order to increase control and decrease symptoms and discomfort; (b) enhance the coping ability of the patient by teaching them to recognize and avoid distorted thinking and catastrophizing, and how to use positive coping self-statements; and (c) teach the patient how to use relaxation and imagery. Each of the components of the CCSP have been tested separately and found to be effective in reducing individual symptoms associated with diagnosis and treatment of cancer[7,9,22], but have not tested as a combined comprehensive strategy to treat multiple symptoms. This was the first study to combine these cognitive-behavioral strategies to treat breast cancer patients undergoing ABMT.

Instrumentation

The Sociodemographic Questionnaire used in this study included the variables listed in Table I. The follow-up period was 3 years after the study started accruing subjects.

STATISTICS

Preliminary analysis of the data included exploratory data analysis to ascertain data quality, handle outliners and missing data, and measure group differences among socio-demographic characteristics, disease stage, types of chemotherapy, follow-up time since ABMT, and mean survival time. Chi-square statistics were used to measure the independent association of proportion between CCSP and their controls. In our second stage of analysis we assessed the likelihood of mortality (crude O.R. and 95% CI) between CCSP and their control, and the odds of death among categories that were considered as covariates in the subsequent multiple regression analysis. In this stage of analysis, we also combined the categories of follow-up period since ABMT, thus comparing the odds of death between 1 - 3 years of follow-up and those who were followed up to one year since receiving ABMT. In addition to the bivariate analysis, we assessed group differentials in survival time since ABMT using Kaplan-Myer survival curves. Our final phase of analysis included multiple logistic regression analysis where the probability of mortality was assessed between CCSP and control groups after adjusting for all the covariates in the preliminary analysis. All analytical phases were carried out using SPSS[23].

RESULTS

Fifty-two (47 %) patients received a CCSP and 58 were in the control group (Table 1). The majority of the patients were 41 to 50 years old. There was a statistically significant difference in death rate between the patients receiving the CCSP and the control groups (p<0.05).

Table I Here

Ninety percent in the CCSP group compared to 57% in the control group were married ($p<0.01$). The control group had a statistically significantly lower annual household income ($p<0.05$) than the CCSP group. Forty percent in the CCSP group compared to 21% in the control group had practiced some earlier coping methods ($p<0.05$). There were no statistically significant differences between the groups with regard to stage of the disease and type of chemotherapy treatment (Table I). The rate of patient accrual at follow-up since ABMT did not differ significantly between the two groups. Women with Stage III or IV disease were mainly entered on a trial of IL 2 augmentation of induced autologous GVHD after Cyclophosphamide/Thiotepa (C/T), and women with Stage II disease were mainly entered on a trial of GVHD induction after Cyclophosphamide/Thiotepa/Carboplatin (C/T/Carboplatin) (figure 1).

Figure 1 Here

A total of 16 patients (14.5%) had died when follow up was carried out. When stratified by group, 4 patients in the CCSP group (7.7%), compared to 12 in the control group (20.7%) had died at follow up (Table I). This difference was statistically significant ($p<0.05$). The mean survival period was 496.7 days for the CCSP group compared to 486.8 days for the control group at follow-up. The odds ratio for mortality among the CCSP group was 0.32 ($p<0.06$) (Table II).

<center>**Table II**</center>

Mortality

Table II describes the distribution of metastatic stages, types of chemotherapy received, follow-up period since receiving ABMT and potential sociodemographic risk factors and their association with mortality. It also displays the crude odds ratio and its 95% confidence interval for mortality between CCSP patients and controls. Patients who were followed up two to three years since ABMT were 8.5 times more likely to die than those who had their ABMT up to one year at follow up. A combined follow up period of one to three years placed the patients at a mortality risk of 4.5 (95% CI: 1.0-21.1; p<0.05). As expected patients who had a metastatic stage IV breast cancer were 4 times (95% CI: 1.3-12.8; p< 0.05) more likely to die than patients diagnosed with stage II disease. Patients receiving C/T chemotherapy prior to ABMT were significantly more likely (O.R=0.05, 95% CI=0.0-.4, p<0.01) to die than those receiving C/T/Carboplatin (Table II). All of the above variables with significant association with mortality and traditional sociodemographic factors were subsequently entered into a multiple logistic regression model for measuring the final group differential in mortality. Table III shows that CCSP patients were 9% (95% CI=0.01-0.81) less likely to die (p<0.05) when adjustments were made for demographics, metastatic stage, type of chemotherapy and previous practice of coping and relaxation methods, and follow up period of 1 to 3 years (Table III).

<center>**Table III Here**</center>

Figure 2 presents the survival probabilities at follow-up since ABMT between CCSP and

the control groups. In general, the CCSP group shows a better chance of survival than the control group. Furthermore, the control group had a larger decline in the survival slope between 200 to 400 days at follow up since ABMT than the CCSP group, thus widening the overall difference in survival between the groups at 3 year follow up.

_____

Figure 2 Here

_____

DISCUSSION

As hypothesized, patients with breast cancer who underwent bone marrow transplant and received the CCSP, were less likely to die than the comparison group (7.7% vs. 20.7%). This difference was both clinically and statistically significant. Significant group differences were observed even after the two important contributors of mortality: disease stage and chemotherapy type, were controlled ($p < 0.05$). The results of survival between groups, however, need to be interpreted with caution. In order to examine the data for bias, the following steps were taken.

Interaction Effects

Our first step was to assess the extent to which preferential selection into a particular chemotherapy might have influenced our results. Fifty-seven percent of the patients in the control group received C/T, compared to 42% in the CCSP group, while 43% in the control group received C/T/Carboplatin, compared to 58% in the CCSP group (fig. 1). Although large differences in chemotherapy type were observed between groups, these group differences were not statistically significant. Further, no statistically significant group differences were observed when comparisons were made between CCSP treatment and disease stage among those patients receiving C/T/Carboplatin, indicating no preferential treatment of a specific chemotherapy

between CCSP groups. However, when comparison was made between disease stage and chemotherapy type, significant differences were observed (p<0.001), regardless of CCSP group assignment. This difference remained significant at p<0.04 level when group differences were compared for CCSP group and their controls separately (fig. 1). Significant group differences (p<0.01) were observed for mortality, when proportions of those receiving different CCSP and chemotherapy types were compared. Disease stage and CCSP treatment also interacted with each other (p<0.05) on mortality at the bivariate level. These findings suggested that the differential accrual of patients with different metastatic disease stage to the two CCSP groups, may have masked the true relationship of the CCSP effects on mortality. Indeed, upon further investigation of the study protocol, we observed that, of these patients, the majority of the first 41 accrued (approximately the first 18 months of the CCSP study protocol) to the study were administered C/T according to a study protocol, while patients were randomly assigned (as part of a second study protocol) to receive either C/T or C/T/Carboplatin during the second phase of the CCSP study (approximately 18 months to 3 year of the CCSP study protocol). Patients recruited in the earlier phases of the study were also classified as disease stages III or IV only, while a large number of stage II patients were recruited to the autotransplant program toward the latter part of the CCSP study. There was no way of avoiding patient recruitment from the new chemotherapy (C/T/Carboplatin) treatment protocol without sustaining sample loss and inadequate statistical power, given the short time period of patient accrual to the CCSP study protocol.

Multivariate Models

Two independent predictors of mortality emerged from our final multivariate analysis: CCSP treatment (O.R. 0.0921, 95%CI 0.0105-0.8062, p=0.0312) and treatment with C/T/Carboplatin (O.R. 0.0241, 95%CI 0.0009-0.6597, p=0.0274). Results from our bivariate

analysis, and the emergence of two independent predictors influenced our decision to further

investigate interactions between CCSP and chemotherapy treatments on mortality during the

multivariate analysis. In a separate multivariate analysis, we also investigated for interaction

between disease stage and CCSP treatment on mortality. Finally, in a third model, we tested for

a 3-way interaction among CCSP treatment, disease stage and chemotherapy type on mortality.

Such analyses would also help us understand any potential selection bias which may have been

introduced in the study due to chemotherapy protocol changes, and masked the true effects of the

CCSP treatment. In all these three subsequent multiple regression equations, the main effects of

CCSP treatment became non-significant, while the main effects of chemotherapy

(C/T/Carboplatin) had statistically significant negative effects on mortality in both the 2-way

interaction models (O.R. (95%CI): 0.0308 (0.0011-0.8978) and 0.0579 (0.0039-0.8556)

respectively). The main effects of the chemotherapy, and the effects of the CCSP treatment

disappeared when 3-way interactions among CCSP, disease stage, and chemotherapy treatment

were tested. These tests indicated the possibility of some bias due to chemotherapy protocol

changes administered along with the CCSP treatment protocol. Although there was no

significant interaction effects between CCSP and chemotherapy type, CCSP and disease stage, or

CCSP, disease stage and chemotherapy type, extremely small samples in each of the 2-way and

3-way interaction groups also rendered the models unstable, thus limiting an elaborate discussion

of bias among each of these sub-groups, while controlling for extraneous factors in the

multivariate models.

Addressing Bias Due to Metastatic Disease Stage and Protocol Changes in Chemotherapy
Treatment

In order to address the issue of chemotherapy changes and thus estimate the unbiased

effects of CCSP treatment, we applied a simple method of handling patients who had been either diagnosed with disease stage II or those who received C/T/Carboplatin as a part of their chemotherapy (these were the two groups which were incorporated into the CCSP study protocol at a later stage). We excluded this group from our analysis. As a result, fifty patients were in the final study sample whose likelihood of mortality was examined as an effect of CCSP treatment. Although the sample size was less than half of the original study sample, our purpose was to determine whether CCSP was effective on mortality on this sub-set of uncontaminated sample. Multiple logistic regression analysis revealed that patients receiving CCSP were still 9% less likely to die (O.R. 0.0919, 95%CI 0.0087-0.9671, $p=0.0468$) than their comparison group, after adjustments were made for covariates, including disease stage. In a separate multivariate analysis, using the total sample, patients in the CCSP group were less likely to die ($p<0.05$) when statistical adjustments were made for patients who received C/T/Carboplatin or those who were diagnosed with disease Stage II. The group difference was statistically significant, in both analysis, thus demonstrating the CCSP may have been useful to a small but significant group of patients in preventing mortality at the time of follow-up. The mechanism of action regarding the CCSP requires further study. There is also a need to determine if the CCSP is effective in other cancer patients receiving chemotherapy.

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Table I

Differences in Sociodemographics, mortality, disease stage and chemotherapy type between CCSP@ and their controls among ABMT breast cancer patients

Attributes	CCSP (N=52) n(%)	Control(N=58) n(%)
Deaths	4(7.7)	12(20.7)*
Follow-up since ABMT		
2-3 years	15(28.8)	20(34.5)
1-2 years	18(34.6)	18(31.0)
up to 1 year	19(36.5)	20(34.5)
Age 22-40 years	11(21.2)	17(29.8)
41-50 years	26(50.0)	32(56.2)
51 years and over	15(28.8)	8(14.0)
Race - White	46(88.5)	48(82.8)
Employment Status - Employed	38(73.1)	36(62.1)
Marital Status – Married	47(90.4)	33(56.9)**
Education =< High School	8(15.4)	10(17.5)
Some College	10(19.2)	18(31.6)
College/Graduate degree	34(65.4)	29(50.9)
Occupation – Professionals	34(65.4)	32(55.2)
Income -- Less than 50K	10(19.2)	22(37.9)*
Cancer Stage Stage II	8(15.4)	13(22.4)
Stage III	32(61.5)	28(48.3)
Stage IV	12(23.4)	17(29.3)
Chemotherapy type I Cyclophosphamide/Thiotepa (C/T)	22(42.3)	33(56.9)
II C/T/Carboplatin	30(57.7)	25(43.1)
Prior Coping Methods	21(40.4)	12(20.7)*
Prior Relaxation Methods	20(38.5)	18(31.0)
Mean Survival Period(days)(s.d.)	496.7(283.4)	486.8(322.7)
Median	495.5	424.5
Range Days	90 to 1027	19 to 1132

@ Comprehensive Coping Strategy Program
* p <0.05   ** p<0.01

Table II

Association of intervention, year since follow-up , breast cancer stage, chemotherapy type, participant characteristics and mortality among ABMT breast cancer patients

Attributes	Deaths n (%)	O.R. (95%CI)
Intervention(CCSP)@	4 (7.7)	0.32(0.1-1.1) †
Follow-up since ABMT		
2-3 years	11 (31.4)	8.5(1.7-41.6)**
1-2 years	3 (8.3)	1.7(0.3-10.7)
up to 1 year	2 (5.1)	1.0
1-3 years	14 (19.7)	4.5(1.0-21.1)*
Age 22-40 years	1 (3.6)	0.2(0.2-1.3)
41-50 years	11 (19.0)	1.0
51 years and over	4 (17.4)	0.9(0.3-3.2)
Race - White	14 (14.9)	1.2(0.2-6.0)
Employment Status - Employed	9 (12.2)	0.6(0.2-1.7)
Marital Status - Married	14 (17.5)	3.0(0.6-13.9)
Education =< High School	4 (22.2)	2.8(0.7-11.1)
Some College	6 (21.4)	2.6(0.8-9.1)
College/Graduate degree	6 (9.5)	1.0
Occupation – Professionals	5 (7.6)	0.2(0.1-0.8)*
Income - Less than 50K	2 (6.3)	0.3(0.1-1.4)
Cancer Stage Stage II	1 (4.8)	0.4(0.1-4.0)
Stage III	6 (10.0)	1.0
Stage IV	9 (31.0)	4.0(1.3-12.8)*
Chemotherapy type I Cyclophosphamide/Thiotepa (C/T)	15 (28.8)	1.0
II (C/T/Carboplatin)	1 (1.8)	0.05(0.0-0.4)**
Prior Coping Methods	2 (6.1)	0.3(0.1-1.4)
Prior Relaxation Methods	4 (10.5)	0.6(0.2-2.0)

@ Comprehensive Coping Strategy Program
† p<0.06
* p <0.05   ** p<0.01

Table III

Adjusted Probability of Mortality Associated with CCSP@ treatment among Breast Cancer Patients Undergoing ABMT

Attributes	Odds ratio (95%CI) (Full Sample: N=110)	Odds ratio (95%CI) (Reduced Sample: N=50)
CCSP	0.09(0.01-0.81)*	0.09(0.01-0.97)*
Age 22-40 years	0.10(0.0-2.6)	0.24(0.01-4.55)
41-50 years	1.0	1.0
51 years and over	0.89(0.1-7.9)	1.40(0.08-23.84)
Race - White	0.79(0.1-8.6)	0.28(0.02-4.22)
Employment Status - Employed	0.63(0.1-4.0)	1.17(0.14-9.66)
Marital Status - Married	1.91(0.1-27.4)	2.13(0.12-32.95)
Education =< High School	3.34(0.2-52.7)	2.45(0.12-48.17)
Some College	2.02(0.2-20.9)	1.01(0.0911.86)
College/Graduate degree	1.0	1.0
Occupation – Professionals	0.16(0.0-1.4)	0.08(0.01-0.99)
Income - Less than 50K	0.06(0.0-0.8)*	0.08(0.01-1.04)
Cancer Stage Stage II	0.17(0.0-4.9)	NA
Stage III	1.0	1.0
Stage IV	3.05(0.5-19.3)	1.76(0.24-12.76)
Chemotherapy type I Cyclophosphamide/Thiotepa (C/T)	1.0	NA
II (C/T/Carboplatin)	0.02(0.0-0.6)*	NA
Prior Coping/Relaxation Methods	0.18(0.0-3.4)	1.09(0.16-7.54)
Follow-up since ABMT 1-3 years	0.61(0.0-3.9)	0.36(0.01-16.60)
Hosmer - Lemeshow Goodness of Fit	Chi-square 5.2, df:8, p=0.73	Chi-square 5.8, df:8, p=0.67

@ Comprehensive Coping Strategy Program   NA: Not applicable due to exclusion
* p<0.05

Appendix 7

The Impact of the Comprehensive Coping Strategy Program on Quality of Life of Breast Cancer Autologous Bone Marrow Transplantation Patients

The Impact of the Comprehensive Coping Strategy Program on Quality of Life of Breast Cancer Autologous Bone Marrow Transplantation Patients

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Introduction

The American Cancer Society estimates 175,000 new cases of female breast cancer in the United States in 1999, and that 43,300 women will die from this disease (1). There are also currently almost two million breast cancer survivors in the United States (2). Breast cancer survivors are challenged to redirect their energy from issues of cancer treatment and side effects to quality of life (QOL) issues related to survivorship (3). Potential psychological, sexual and physical dysfunction caused by both the diagnosis and treatments can have a deleterious impact a woman's QOL. These challenges have increased attention on these QOL issues by the media, consumer groups, and the scientific community (2).

The ABMT treatment uses high dose chemotherapy followed by rescue with either bone marrow or peripheral blood stem cell transplantation in an attempt to prolong survival and disease-free survival (4). Breast cancer patients who undergo this treatment must cope not only with a life-threatening medical treatment, but also with multiple, interrelated symptoms such as pain, anxiety and depression that affect their QOL (5,6). The overall purpose of this study was to examine the effectiveness of the Comprehensive Coping Strategy Program (CCSP) on QOL in patients who underwent autologous bone marrow transplantation (ABMT) for breast cancer.

Literature Review

<u>Quality of Life</u>

Ferrell (7, p. 915) concluded, through a synthesis of her QOL program of research that "QOL is a personal sense of well-being encompassing physical, psychological, social, and spiritual dimensions". QOL refers to patients' appraisal of and satisfaction with their current level of functioning compared to what they perceive to be possible or ideal. It is a dynamic, multifaceted process through which perceptions, viewpoints, and behaviors change as a result of

2

the various experiences throughout the survival period. Although there remains a lack of conceptual agreement regarding QOL, experts agree that QOL incorporates patients' subjective experiences and is multidimensional in nature (8).

The increased interest over the past two decades in the outcome of QOL is related to increased disease and disease free survival times, concerns for patient tolerance of the more common use of aggressive treatments such as ABMT, as well as patients' willingness to participate in clinical trials (8). Investigators are interested in measuring QOL in cancer patients generally to assess rehabilitation needs, as an end-point in evaluating treatment outcome, and as a predictor of response to future treatment (9). Thus, QOL becomes an important aspect of the cost/benefit ratio in evaluating treatment recommendations based on clinical trial data.

Several instruments have been developed to measure QOL in cancer patients, but none has been universally accepted (10). Although there is consensus regarding the importance of QOL as an outcome variable in cancer treatments, there is still no general agreement on what it is, or how such studies should be conducted (11). Aaronson (12) supports the need for QOL instruments that are theoretically-based, increased application on QOL in clinical trials, and the need for measures relevant to the population in question.

QOL of breast cancer patients after various treatment modalities has been explored. There exists, however, a general paucity of baseline data. Ganz et al. (13) reported that breast cancer survivors reported severe rehabilitation problems following surgery, regaining maximum recovery by one year after surgery. Wyatt and Friedman (14) investigated the patterns of functioning and psychosocial adjustment of midlife and older women following surgery for breast cancer. Baseline data and differences between those who received follow-up adjuvant therapy and those who did not

also were compared. Follow-up data were obtained at six weeks, three months, and six months post-surgery. No differences existed between the two treatment groups at baseline, with the exception of lower functional status reported by the surgery-only group. In the surgery-only group, functional status improved significantly from six weeks to three months post-surgery. The most frequently reported symptoms of both groups included fatigue and pain. These results suggest that both groups did equally well, regardless of whether they received adjuvant therapy (radiation or chemotherapy). Neither QOL nor demands of illness differed between the two groups, nor did these scores change significantly over time following surgery. These post-surgery findings are applicable to the ABMT population because transplantation may occur within this time period after surgery.

Survival issues for patients treated for breast cancer may be viewed through the four domains of QOL as conceptualized by Ferrell, Grant, Funk et al. (2): physical and social well-being (2); and psychological and spiritual well-being (15). Psychological well-being was defined by Ferrell (16) as "seeking a sense of control in the face of life threatening illness characterized by emotional distress, altered life priorities, and fears of the unknown, as well as positive life changes". Spiritual well-being is characterized frequently in terms of existential and religious dimensions. This encompasses feelings of uncertainty, hopefulness, purpose for living, positive spiritual changes, increased life meaning, and the importance of spiritual activities.

Ferrell, Grant, Funk et al. (17) explored these domains in a group of 21 breast cancer survivors. In the domain of physical well-being, menstrual and fertility changes, fatigue and pain were of concern. The domain of psychological well-being was influenced by numerous fears, including cancer recurrence, spread, or a second cancer, and impacted on self-concept. The social well-being scale showed the greatest problem in the area of family distress, and the spiritual well-being subscale showed disruption in the area of uncertainly with some aspects rated positively, such

as religious activities. Lee (18) found that social support played an important role in promoting overall QOL in a sample of 100 breast cancer survivors who had undergone mastectomies.

In a Swedish study by Larsen et al. (19), functional capacity and health-related QOL were investigated in nine women with breast cancer undergoing ABMT. The ABMT primarily affected their self-rated physical health and functions. Their physical health status was reported to be poorest at discharge. The women's emotional status was reported to be poor throughout the entire study period. Hann et al. (20) compared QOL reported by women treated with ABMT with a group of women of similar age without a history of cancer. The ABMT group has significantly impaired physical functioning, physical role functioning, general health , vitality, social functioning, and emotional role functioning. Impaired QOL following BMT (20) was significantly associated with lower income, a longer time to engraftment, longer hospital stay, poor performance status, and greater symptom prevalence, severity, and distress. In contrast to these findings, Whedon, Stearns, and Mills (21) reported from a cross-sectional, descriptive study (n=29) that the majority of breast cancer ABMT survivors reported few physiological disruptions and above average QOL.

QOL is used to assess treatments in clinical trials and may be influenced by multiple symptoms and related factors. Cultural and biomedical factors may influence baseline QOL and should be considered when evaluating the impact of treatment on QOL. Marshall (22) cautions us that careful attention should be given to the subtle nuances of language and the sociocultural context of questionnaires in QOL research (1990). Pain (24-35), anxiety (27,28, 30, 31, 37-39, 40, 41) and depression (27, 28, 30, 31, 36, 39) have been documented in the scientific literature as symptoms experienced by cancer patients undergoing ABMT and are significantly correlated to each other.

There are few intervention studies focusing on improving the QOL of breast cancer patients that use a clinical trial design. One such study examined the effect of a psychological intervention

on the QOL and behavior of women diagnosed with breast cancer (23). Thirty-six consecutive patients with non-metastatic breast cancer assigned to surgery and systemic chemotherapy were randomized to receive either psychological intervention (weekly cognitive individual psychotherapy and bi-monthly family counseling) or standard follow-up. Cognitive psychotherapy and family counseling improved both depression and QOL indexes compared with the control group. Better emotional coping behaviors were also revealed by some changes in personality traits in the intervention group (23). It is known that the development and utilization of effective coping skills is likely to improve the patients QOL (42).

In summary, breast cancer survivors experience many demands of illness across all QOL domains and are in need of comprehensive care and targeted interventions. Assessment of QOL deficits can help identify patients who might benefit from psychosocial interventions. Research studies using experimental designs are needed to clarify the effectiveness of these interventions.

Theoretical Support for the Comprehensive Coping Strategy Program

The Gate-Control Theory of Pain by Melzack and Wall (43) and the Stress, Coping and Adaptation Paradigm by Lazarus (44, 45, 46) provide the theoretical framework for use of the CCSP. Pain is defined as a multi-dimensional sensory and affective experience associated with discomfort (47). According to the Gate-Control Theory, the central system located in the brain can be stimulated by cognitive processes, past experiences, anxiety, anticipation and attention, which open the gating mechanism permitting the transmission of nociceptive impulses to the brain (43).

Coping is defined as constantly changing cognitive and behavioral efforts used to manage specific external and/or internal demands that are appraised as taxing or exceeding the resources

of a person (44). Positive coping strategies refer to internal thoughts and behaviors people use to manage their pain, or their emotional reactions to the pain and to reduce emotional distress. Catastrophizing, a negative coping strategy, is defined as a method of cognitive coping characterized by negative self-statements and thoughts about the future (48). Negative thoughts have been associated with negative health outcomes.

Several coping strategies have been shown to be effective in one's QOL by reducing multiple symptoms such as those experienced by breast cancer patients who undergo ABMT. They are: a) preparatory information to increase control (49); b) cognitive restructuring which includes positive coping statements and avoidance of catastrophizing (49, 50); and c) relaxation with guided imagery (51,52,53). Progressive muscle relaxation and imagery (52) have been found to help patients to either escape the problem or think of the problem in alternative ways. Cognitive behavioral training helps develop coping skills and lessens the anxiety and depression which may exacerbate the symptom (55). The efficacy of relaxation and psychological counseling is well-established (55).

Cognitive-behavioral strategies are used most frequently to improve QOL by helping to control a wide range of multiple symptoms such as pain, fatigue, anxiety, depression, and nausea (53, 54). Symptomatology related to high-dose chemotherapy and ABMT can be distressing over time and can decrease a woman's QOL. It is important to teach the patient coping strategies prior to treatment, and to regularly reinforce these strategies during the course of treatment (56).

No prospective or retrospective study was found in the scientific literature that included a comprehensive coping strategy program (CCSP) to improve the QOL of breast cancer ABMT

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patients. Therefore this is the first study to examine the effectiveness of a multi-modal CCSP in this population. The following questions were addressed in this study:

1. Do breast cancer patients who undergo ABMT find the CCSP beneficial?

2. Are there significant correlations between baseline scores of QOL, anxiety, depression, health locus of control, coping strategy constructs and QOL at follow?

3. Do breast cancer patients who undergo ABMT and are treated with a CCSP have higher quality of life at one-year follow-up than breast cancer patients who undergo ABMT but do not receive a CCSP?

Methodology

Design

This study used an experimental design with random assignment to one of two possible groups. Thus it was a randomized, controlled prospective clinical trial. Participants were randomized to one of the following two groups: Group I: Patients scheduled for ABMT who received a CCSP (treatment group); or Group II: Patients scheduled for ABMT who did not receive the CCSP (control group). Both groups received usual medical treatment and nursing care.

Sample and Setting

The study was approved by the Institutional Review Board prior to participant accrual. All participants were recruited by either the physician or the bone marrow transplant (BMT) clinical nurse specialist during a regularly scheduled pre-ABMT Medical Oncology Outpatient Clinic visit. All participants had been accepted into the ABMT program prior to the invitation to participate in this study. Written informed consent was obtained from each participant before data was collected.

A consecutive sample of 128 women with stage II, stage III, or stage IV breast cancer who were scheduled for ABMT at an urban National Cancer Institute designated comprehensive cancer center located in Eastern United States agreed to participate in the study. Eligibility criteria for subjects included a diagnosis of stage II, III, or IV breast cancer, scheduled for ABMT, age 18 years or older, and able to read and write English. Eighteen subjects did not meet this criteria (3 had their ABMT canceled, 10 subjects refused to participate after they had signed consent forms, and 4 subjects were too ill to participate in the CCSP). The final sample was 110 subjects.

Procedure

The subjects completed the baseline questionnaires in a quiet, comfortable room located in the outpatient clinic. Patients were told that they could take a break at any time during data collection. The BMT clinical nurse specialist provided the baseline questionnaires, answered participants' questions, and retrieved the questionnaires after completion. It took approximately one hour for the subjects to complete the questionnaires.

The CCSP was reinforced on the same day the patient was admitted to hospital, 2 days after completion of chemotherapy, and 7 to 9 days after the ABMT. The CCSP intervention (handouts and audiotapes) was reinforced according to protocol in all subjects who remained in the study. In addition, patients were instructed to use the CCSP at least once a day during hospitalization on a routine basis. The patients in the treatment group were also instructed to identify other situations in which they felt that the CCSP intervention was helpful and to record in the diary the situation in which the CCSP handouts and audiotapes were used. The patients were also instructed to document whether or not the CCSP intervention was beneficial in relieving their symptoms. An experienced

ABMT oncology nurse, the principal investigator, or the Project Director provided the reinforcement. QOL questionnaires were mailed to participants twelve months after discharge from the hospital.

CCSP Intervention

The CCSP was taught to patients in the treatment group by a clinical social worker at least two weeks prior to hospital admission for treatment with high-dose chemotherapy and ABMT. Preparatory information was presented which stressed that adequate control of pain can lead to decreased psychological distress and a decrease in physical symptoms other than fatigue. Handouts were given to each participant regarding ways to participate in reducing pain and psychological distress and general ways to increase control. Theoretical considerations regarding treatment of pain were presented including; definition of pain; three components of pain; a brief explanation of the Gate Control Theory; and theoretical reasons why increasing control through use of the coping self-statements and relaxation with guided imagery can decrease pain and emotional distress. A handout explaining ways to help reduce pain was given to each subject. Cognitive restructuring information focused on the avoidance of catastrophising, distorted thinking, and the use of positive coping self-statements. Two handouts were used which explained styles of distorted thinking to avoid and 15 positive coping self-statements.

Relaxation with guided imagery was presented on video tape in a participant modeling format. Participants were taught how to do a brief muscle relaxation procedure, and cue-controlled relaxation with the word "relax". Imagery was introduced into the relaxation exercise. At the completion of the session two handouts were given to the participants which presented how to use relaxation therapy and the benefits of relaxation therapy. A small hand held audiotape recorder

with ear phones and an audiotape was given to each participant. The purpose of this tape was to guide the participants in active participation in the relaxation exercise. Participants were instructed to use the 5 minute audiotape at least every day and prior to stressful events.

Instrumentation

Sociodemographic variables: The Sociodemographic Questionnaire included the following items: age; gender; race/ethnicity; marital status; educational level; religion; patient living arrangements; average yearly household income; occupation; work status; household income; type of chemotherapy, breast cancer stage; and the subjects' previous use of relaxation and coping strategies.

Pain: The Painometer ®(POM), which was designed to assess patients' overall pain intensity and intensity of the sensory and affective components of pain, as well as the quality of pain (57). The POM is a hard, white plastic tool which measures 8 inches long, 2 inches wide, and 1/4 inch thick. It is light weighted and is held easily by the subject. A list of 15 sensory and 11 affective pain descriptors is located on the front side of the POM and a 100mm visual analogue scale (VAS) with a moveable marker (POM-VAS) is located on the backside of the POM. An intensity value (from a low of "1" to a high of "5") is predetermined for each sensory and affective word located on the POM-WDS. A maximum score of 36 can be obtained for the sensory component of pain and of 34 for the affective component. A total score can be obtained by adding the sensory and affective scores. High correlations were found between the initial and the repeat pain intensity ratings on the POM-VAS ($r = 0.88$, $p < 0.001$) and the POM-WDS ($r = 0.84$, $p < 0.001$) (test-retest reliability). Correlations between the POM-WDS and the McGill

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Pain Questionnaire (r = 0.69, p < 0.001) and POM-VAS (r = 0.85, p < 0.001) supported the concurrent validity of the POM-WDS. Construct validity was supported for the POM by showing that pain scores decreased significantly for the POM-WDS (t = 5.53, p < 0.001), and the POM-VAS (t = 6.18, p < 0.001) after the treatment with pain medication. The POM took about 2 minutes to complete.

Psychological Distress: a) Anxiety: The State-Trait Anxiety Inventory (STAI) (58) was used as one measure of psychological distress. The STAI consists of two separate self-report scales for measuring state and trait anxiety (58). State anxiety is a transitory emotional response to a stressful situation. Trait anxiety reflects a stable predisposition to anxiety as determined by a personality pattern. Each scale consists of 20 statements related to emotions and requires 5 to 10 minutes to complete. Respondents rate themselves in relationship to the statement on a Likert scale from 1 to 4. The total score is the sum of all 20 responses and ranges from a minimum score of 20-39 (low anxiety), 40-59 (moderate anxiety), to a maximum score of 60-80 (high anxiety). Scores are reported to be considerably higher under stress conditions than under normal conditions (58). Test-retest reliability correlations reported for the trait scale ranged from .73 to .86, as opposed to the range of .16 to .54 for the state scale (58). Construct validity of the STAI has been demonstrated (58); b) Depression: The Beck Depression Inventory (BDI) (59) was used to measure psychological distress. The BDI consists of 21 items that describe particular symptoms of depression (59). Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores ranging from 0 to 9 are normal, 10 to 15 mild depression, 16 to 23 moderate depression, and 24 to 63 severe depression. The total score (range 0 to 63) is obtained by summing the 21 responses. Test-retest correlations

of the BDI ranged from .60 to .90 in non-psychiatric patients (59). Content and construct validity have been demonstrated for the BDI (59).

Quality of Life: The Quality of Life Index-Cancer Version (QLI-CV) will be used to measure QOL in the participants (60). The QLI-CV consists of 2 parts: Part 1 measures satisfaction with various domains of life and; Part 2 measures the importance of the same domains to the subject. For example, a Part 1 item asks "How satisfied are you with your health?" and a Part 2 item asks "How important is your health to you?". Both parts are composed of 35 items that address the following domains of life: health and functioning; socioeconomic aspects; psychological/spiritual and; family. Subjects respond to items on six-part Likert-type scales, ranging from "very satisfied" (6) to "very dissatisfied" (1) for Part 1 items and from "very important" (6) to "very unimportant" (1) for Part 2 items (60). The range possible for the overall scores and subscale scores is 0 to 30. Validity and reliability have been reported for this test.

Coping strategies: The Coping Strategy Questionnaire (CSQ), developed by Keefe (48) will be used to assess patients' use of coping strategies. The categories of coping strategies assessed by this measure include: (1) diverting attention; (2) reinterpreting pain sensations; (3) ignoring pain sensations; (4) praying and hoping; (5) catastrophizing; and (6) increasing activity level. For each category of coping strategies there are 6 items on the CSQ with scores ranging from 0 to 36. Each item is rated on a 7 point scale to indicate how often that strategy is used to cope with pain (0 = never, 3 = sometimes, and 6 = always). The CSQ also includes 2 items which measure overall effectiveness of those strategies used by asking the subjects to rate on a 7-point scale (with scores ranging from 0 to 6) how much control they have over the pain, and how much they are able to decrease their pain. Reliability and validity have been reported for this tool.

Statistical Analysis

Preliminary analysis of the data included exploratory data analysis to ascertain data quality, handle outliers and missing data, and measure group differences among sociodemographic characteristics, disease stage, and types of chemotherapy. Descriptive statistics (frequency, percent, mean, median, and standard deviation) were used to describe the sample and responses to the instruments. Final phase of analysis included multiple regression analysis to assess differences between CCSP and control groups after adjusting for covariates and controlling for demographic variables.

We tested the effectiveness of CCSP on the 12-month follow-up QOL measures by undertaking the following statistical/analytical steps: 1) Descriptive statistics were used to describe the sample characteristics and the use of the CCSP, and the benefits of the CCSP for the treatment group. Initial distribution and independent association of proportions to test differences between CCSP and control groups at baseline, by using chi-square tests. Mean differences between groups were also tested both at baseline and follow-up for all outcomes as well as co-variates. 2) Correlation between outcome scores at follow-up and baseline psychological scores were carried out by using zero-order correlations to determine strength of association. The extent of multi-colinearity among covariates, and interaction factors, if any existed, were also tested as a part of the second step. 3) Simple linear regressions assessed the influence of treatment at a crude level. Subsequent hierarchical regression models were tested by incrementally introducing different conceptually plausible factors while accounting for the subject's baseline status on the outcome(s), and by using analysis of covariance (ANCOVA) methods. Sequential steps in this phase of the analysis helped us determine the level of hierarchy where the CCSP had maximum effect on the overall QOL scores and its sub-scales. Such a step also gave us the advantage to assess the best fitting model that can be

derived, within the limitations of the constructs available in the databases. Measures within each of the hierarchy were kept constant in order to compare and contrast the differences in the standardized coefficients and variance among total scores and sub-scales and also to assess the increment or decrement of the effectiveness of treatment.

Results

Subjects

The sociodemographic characteristics at baseline of patients (CCSP, N=38, control, N=35) followed-up a year or more are presented in Table 1. This sub-sample is comparable with the overall sample of 138 subjects. The major characteristics are that the subjects are 41 - 50 years of age, white, college graduates, and professionals with incomes above $50,000. Most subjects were married, employed, and were diagnosed with stage III breast cancer. There were no significant differences between the CCSP treated group and the control group regarding demographic characteristics at baseline.

Table 1 about here

Benefits of the CCSP Intervention from the Patients Perspective

It was interesting to note the time of day and the situations in which the patient chose to use the CCSP handouts and audiotapes. The most frequent use of the CCSP intervention was during the evenings around bedtime. The most frequent symptoms/ problems for which the patients used the CCSP intervention were psychological problems (51%) and sleep problems (60%). Twenty one percent of the patients used the CCSP to deal with chemotherapy side effects. The CCSP handouts and audiotapes were used 385 times by the patients. Both the handouts and the audiotapes were

beneficial based on the patients reports. However, the patients documented the CCSP audiotapes as more beneficial. The audiotapes were used over 50% more often than the handouts. Twenty one (78%) of the patients reported that the audiotapes were effective 90-100% of the time compared to 19 (70%) of the patients reporting that the handouts were beneficial 90 to 100% of the time. Four (15%) of the subjects found the handouts to be beneficial 50 - 89 % of the time compared to 6 (22%) of the subjects reporting the audiotape to be beneficial 50 - 89 % of the time. Four patients reported that the handouts were beneficial less than 50% of the time. The remaining subjects in the treatment group only indicated that they had used the CCSP according to protocol and did not record additional situations in which they had used the handouts and audiotapes.

Description of Study Variables

Anxiety, depression, health locus of control and coping strategies were identified as confounding variables. Mean scores of these constructs are presented in Table 2. The anxiety scores indicated that the patients in both groups experienced mild to moderate anxiety at baseline. The control group reported mild depression. The most frequently used coping strategy in both groups was coping self-statements, followed by praying. Both groups had a mean score of 30 for the construct avoidance of catastrophizing. There were no statistical significant differences between the two groups regarding the study variables.

Table 2 about here

Quality of Life

The mean and standard deviation scores on overall quality of life (QOL) scale and subscales between patients (controls and CCSP treated) at baseline and at one year or more follow-up are

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presented in Table 3. Health functioning, was the only QOL subscale with a score below 20 in both groups. The CCSP treated group had a statistically significantly higher overall quality of life (p<.05), health functioning, and socioeconomic well-being (p<.05), and spiritual wellbeing (p<.01) than the control group at follow-up). Family well-being was lower in the control group compared to the CCSP treated group at baseline and follow-up. This difference was, however, not significant. (Table 3).

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Table 3 about here

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Correlation Between Study Variables at Baseline and QOL at Follow-up

As expected, there were significant correlations among the overall QOL and subscales of QOL. With the exception of a significant correlation between state anxiety and socioeconomic and family well-being, all other QOL scales were statistically significantly correlated to state and trait anxiety and depression (Table 4). There were no significant correlations between health locus of control variables and overall QOL and the subscales of QOL. Coping self-statements, reinterpretation and avoidance of catastrophizing were significantly related to different QOL scales (Table 4).

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Table 4 about here

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Effectiveness of the CCSP

A model measuring the effectiveness of the CCSP on Quality of Life (total and subscale scores) constructs at follow-up a year or more after ABMT among patients with breast cancer is presented in Table 5. The CCSP treated group showed significant improvement in overall QOL (Beta=0.31, p<.01), health and functioning, well-being (Beta=0.24, p<.05), socioeconomic well-being

(Betas=0.25, p<.05), and psychological/ spiritual well-being (Beta=0.36, p<.01) than the control group without any adjustment factor. With incremental adjustment for baseline QOL, disease stage, chemotherapy type, demographics, trait anxiety, coping self-statements and avoidance of catastrophe, and internal/powerful others locus of control and depression (Table 5). The results showed that the CCSP improved the QOL (Beta=0.26, p<.05; R^2= 49%), psychological well-being (Beta=0.28, p<.05; R^2 =51%) and spiritual well-being (Beta=0.39, p<.05; R^2=39%) of breast cancer patients at one year follow-up and more after an autotransplant.

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Table 5 about here

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Discussion

The patients overwhelmingly reported that they found the CCSP intervention helpful. They used the CCSP intervention during critical points in their treatment and on days when they experienced most side effects from the ABMT and found the CCSP intervention to be helpful 90 to 100% of the time. The subjects used the CCSP in situations that are supported theoretically in the scientific literature for use of behavioral treatment strategies such as to decrease their psychological distress, to decrease side effects of chemotherapy, and to induce sleep. Although the CCSP was mainly used during the evenings, it was also frequently used during the afternoons.

The patients used the CCSP audio-tapes more frequently and found them to be more helpful than the CCSP handouts. The increased use of the audio-tapes may be explained by the fact that it is a procedure that has to be followed whereas the handouts support cognitive restructuring. Hopefully, the information in the handouts gradually becomes an automatic part of the subjects' thinking processes, and therefore do not need to be read so frequently. The audio-tapes make relaxation possible through the participation of subjects in a carefully outlined progressive relaxation procedure

combined with imagery. The audio-tapes are also designed to help the subjects become relaxed more quickly as they become more comfortable with the information and instructions on the tape.

The benefits derived from the CCSP, as experienced by the patients, have important implications for clinical practice. The effects of the CCSP may be helpful to a broader group of cancer patients who are treated with chemothearpy for breast cancer but do not receive the ABMT. The audiotape is inexpensive and can easily be used in a variety of situations to help cancer patients cope with psychological distress, and sleeplessness. Clearly, the breast cancer patients in the treatment group in this study have overwhelmingly acknowledged the benefits of the CCSP.

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Table 1
Socio-demographic Characteristics at Baseline of Patients (CCSP and Controls)
Followed up a year or more later (N=73)

Characteristics		Controls		CCSP	
		N	%	N	%
Age	22-40 years	11	32.4	9	23.7
	41-50 years	19	55.9	18	47.4
	51 years and above	4	11.7	11	28.9

Ethnicity	White	30	85.7	34	89.5
	Non-white	5	14.3	4	10.5
Education	High school or less	7	20.6	3	7.9
	Some College	12	35.3	8	21.1
	College grad or higher	15	44.1	27	71.1
Annual Income	Less than 50K	15	42.9	9	23.7
	50K or greater	20	57.1	29	76.3
Marital Status*	Single	14	40	4	10.5
	Married	21	60	34	80.5
Employment	Not employed	13	37.1	8	21.1
	Employed	22	62.9	30	78.9
Occupation	Non-Professional	16	45.7	12	31.6
	Professional	19	54.3	26	68.4
Metastatic Stage	Stage II	9	25.7	5	14.7
	Stage III	15	42.9	19	55.9
	Stage IV	11	31.4	10	29.4
Chemotherapy Type	Cytoxin/Thiotepa	23	65.7	17	50
	Carboplatin	12	34.3	17	50

*P<0.05

Table 2
Mean (+ s.d.) Scores at Baseline on Anxiety, Depression, Health Locus of Control and Coping Strategies Scales and Subscales Among Patients (CCSP and Controls) followed up a year or more later (N=73)

Constructs		Controls		CCSP	
		Mean	s.d.	Mean	s.d.
Anxiety					
	State	39.7	10.5	39.9	11.2
	Trait	38.1	9.2	36.9	8.7
Depression		11.9	8.4	9.9	'6.0
Health Locus of Control					
	Internal	24.8	5	23.9	4.1
	Powerful others	16.3	4.9	16.8	5.5
	Chance	21.4	4.7	20.6	6.1
Coping Strategies					
	Ignoring Pain	14.6	7.7	15.5	8.1
	Coping Self-statements	23.0	6	21.9	6.1
	Reinterpretation	7.0	6.9	7.1	6.8
	Diverting Attention	15.3	8.4	18.1	7.9
	Praying	18.3	7.5	18.8	'8.7
	Behavioral Adaptation	16.9	6	18.2	5.3
	Avoidance of Catastrophy	30.2	5.5	30.5	5.3
	Overall Coping	125.3	26.6	130.1	'31.0

Table 3
Mean (± s.d.) Scores on Quality of Life (QOL) Scales and Subscales
Among Patients (CCSP and Controls) followed up a year or more later (N-73)

QOL Constructs		Controls		CCSP		Total	
		Mean	s.d.	Mean	s.d.	Mean	s.d.
Overall QOL	Baseline	20.6	4.1	22.6	4.3	21.6	4.3
	Follow-up**	21.9	5.0	24.7	3.6	23.4	4.5
Health Functioning	Baseline	18.2	5.5	19.6	6.1	18.9	4.3
	Follow-up*	20.2	5.9	23.0	5.7	21.6	5.9
Socioeconomic	Baseline*	22.7	4.8	24.9	3.5	23.9	4.3
	Follow-up*	23.4	4.9	25.5	3.6	24.5	4.4
Spiritual/Psychological	Baseline*	21.3	5.3	23.6	4.6	22.5	5.0
	Follow-up**	21.3	7.2	25.7	3.9	23.6	6.1
Family Well-being	Baseline*	23.7	5.1	26.3	4.8	25.1	5.1
	Follow-up	26.2	4.1	27.7	3.2	27.0	8.9

*P<0.05   **P<0.01

Table 4
Correlation of Baseline Scores on Quality of Life (QOL), Anxiety, Depression. Health Locus of Control and Coping Strategies Constructs with QOL Constructs at Follow-up Among Patients (CCSP and Controls)

Baseline Constructs   **QOL Follow-up**

Baseline Constructs	Total	HF	SE	Psy/Sp	Fam
Overall QOL (Total)	0.62**				
Psychological/Spiritual (Psy/Sp)	0.56**	0.57**			
Socio-economic (SE)	0.45**	0.29*	0.63**		
Spiritual	0.51**	0.45**	0.42**	0.54**	
Family	0.38**	0.35**	0.27	0.28*	0.45**
Anxiety State	-0.23	-0.24*	-0.12	0.27*	0.01
Trait	0.47**	0.41**	-0.29*	-0.51**	-0.23
	-0.42**	-0.40**	-0.28*	-0.39**	-0.22
Depression					
Health Locus of Control					
Internal	-0.06	-0.05	-0.07	-0.04	-0.01
Powerful others	-0.13	-0.09	-0.02	-0.23	-0.07
Chance	-0.07	-0.08	-0.06	-0.03	0.04
Coping Strategies					
Ignoring Pain	0.18	0.21	0.19	0.04	-0.01
Coping Self-statements	0.13	0.12	0.25*	-0.03	0,05
Reinterpretation	-0.06	-0.08	-0.07*	-0.11	-0.04
Diverting Attention	0.04	0.01	0.1	0.09	-0.10
Praying	-0.12	-0.12	0.21	0.03	-0.80
Behavioral Adaptation	0.08	0.06	0.1	0.1	-0.05
Avoidance of Catastrophy	0.40**	0.35**	0.41	0.33**	0.16
Overall Coping	0.13	0.11	0.18	-0.09	-0.03

*p<0.05   ** p<0.01

Table 5

Hierarchical ANCOVA Models Measuring the Effectiveness of CCSP on Quality of Life (Total and Subscores) constructs at follow-up a year or more after Autotransplant Among Patients with Metastatic Breast Cancer (N=73)

QOL Follow-up

Models Tested with Incremental Adjustment Factor(s)	Overall QOL		Health and Functioning (HF)		Socio-economic (SE)		Psychological/ Spiritual (Psy/Sp)		Family (Fam)	
	Beta[@]	Adj. R^2	Beta[@]	Adj. R^2	Beta[@]	Adj. R^2	Beta[@]	Adj. R^2	Beta[@]	Adj. R^2
1. Unadjusted	0.31**	0.08	0.24*	0.04	0.25*	0.05	0.36**	0.12	0.20	0.03
2. Baseline QOL	0.15	0.38	0.15	0.33	0.08	0.39	0.22*	0.32	0.09	0.18
3. (2) + Disease stage, chemotherapy type	0.18	0.39	0.19	0.35	0.05	0.35	0.26*	0.29	0.15	0.16
4. (3) + Demographics	0.59**	0.48	0.57**	0.47	0.60**	0.41	0.30*	0.32	0.48**	0.16
5. (4) + Trait Anxiety	0.22	0.47	0.23*	0.46	0.02	'0.40	0.33*	0.37	0.18	0.16
6. (5) + Coping Self-Statements and Avoidance of Catastrophy	0.26*	0.49	0.26*	0.47	0.05	0.43	0.37**	0.40	0.20	0.16
7. 6) + Internal/Powerful Others LOC	0.26*	0.49	0.26*	'0.50	0.04	0.41	0.37**	0.37	0.20	0.13
8. (7) + Depression	0.26*	0.49	0.28*	0.51	'0.03	0.41	0.39**	0.39	0.19	0.11

[@]standardized coefficient *P<0.05**P<0.01

Appendix 8

Psychological Distress, Fatigue, Burden of Care, and Quality of Life in Primary Caregivers of Breast Cancer ABMT Patients

Psychological Distress, Fatigue, Burden of Care, and Quality of Life in Primary Caregivers of

Breast Cancer ABMT Patients

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Introduction

Breast cancer patients who undergo autologous bone marrow transplantation (ABMT) must cope not only with a life-threatening medical procedure, but also with multiple, interrelated symptoms including pain, fatigue, psychological distress, and nausea (Gaston-Johansson, Fall-Dickson, et al, 1999; Ford & Ballard, 1988; Gaston-Johansson, Franco, & Zimmerman, 1992). Compounding these stressors is the fact that patients often need to cope with the treatment and symptom experience in an unfamiliar medical center located at a geographical distance from their home. Numerous stressors are also present after the breast cancer patient successfully completes the ABMT and assumes the role of survivor complete with the new fears of recurrence (Zabora, 1998).

Women experience breast cancer and ABMT within a personal context including family support systems. The primary caregiver (PCG), who is the person chosen by the breast cancer patient as her main support person, is an integral part of this family system. Although there is a body of research literature describing pain, fatigue, psychological distress, and quality of life in the breast cancer patient, there is a paucity of literature describing these variables, as well as burden of care, in the PCG (Wochna, 1997). Although the important role of the partner and family in patient care has been recognized, this role has been the focus of few research studies (Jassak, 1992; Rowland & Massie, 1998).

The objectives of this study were to describe and examine relationships among psychological distress, fatigue, burden of care, and quality of life in PCGs of breast cancer patients scheduled for ABMT. This study also examined to what degree psychological distress, fatigue and QOL were predictors of burden of care.

Literature Review

Family Cancer Experience

The literature related to the family's cancer journey may be categorized via four major dimensions: the developmental stage of the family; the cancer illness trajectory; family responses to cancer; and health-care provider behaviors (Kristjanson & Ashcroft, 1994). Families may experience concerns and developmental issues as a function of their developmental stage and age (Kristjanson & Ashcroft, 1994). For example, the developmental stage of the family experiencing breast cancer often includes middle aged PCGs who must constantly balance responsibilities to the breast cancer patient, other family members, and personal life and health.

The cancer illness trajectory in breast cancer is related to the stage of the cancer at diagnosis, time to recurrence, and death. No clear demarcations of the transitional emotional stages which are analogous to the clinical process from diagnosis to cure or from diagnosis to recurrence and death exist for families who experience cancer (Lewis, 1993). However, Giaguinta (1977) and Christ (1983) identified predominant transition points in the cancer experience: diagnosis; treatment initiation; treatment completion; cure; failure to respond to treatment; recurrence; decision to discontinue treatment; terminal illness; and death. Family member concerns may vary with the time since diagnosis and the status of the disease and the patient's condition (Woods, Lewis, & Ellison, 1989). The expected morbidity experienced by the breast cancer patient often corresponds to the ABMT day, with patients experiencing the greatest pain and psychological distress on ABMT day +5 (Gaston-Johansson et al., 1992).

Primary Caregiver Experience

Caregiving is more than just providing physical care for the cancer patient (Laizner, Yost,

Barg, McCorkle, 1993). It is a multifaceted role ranging from mundane responsibilities such as driving patients to treatment appointments to more cognitive actions such as monitoring treatments and recognizing reportable symptomatology to existential moments of sharing the patient's feelings of mortality and uncertainty. Five themes emerged from a descriptive, cross-sectional, qualitative study regarding the role of the caregiver; preparing for caregiving; managing the care; facing challenges; developing supportive strategies; and discovering unanticipated rewards and benefits (Stetz, McDonald, Compton, 1996).

Psychological Distress

Numerous authors have presented data regarding the impact of cancer on the mental health of caregivers. As Hilton (1993, p. 88) explained, "Learning to live with cancer is no easy task. Learning to live with someone else's cancer may be even more difficult." The stresses of providing primary care to the woman with breast cancer are as complex as the distress the patient feels.

Relatives of newly diagnosed cancer patents reported high levels of concerns and psychological distress in a study examining the impact of diagnosis on key relatives of 108 newly diagnosed cancer patients (Harrison, Haddad, & Maguire, 1995). Northouse (1995), in a summary of empiric evidence from 19 studies, reported that families experience parallel emotions to the emotions experienced by women with breast cancer: anxiety; depression; and mood swings. Data from an exploratory study on the mental health (depression), symptoms, and functional status of breast cancer and the mental health (depression) and reaction to care of their caregivers revealed that psychological distress may be more marked in the family member than the patient (Given & Given, 1992).

Northouse (1990), in a longitudinal study of the adjustment of patients and husbands to breast cancer and mastectomy, found that difficulties in psychosocial adjustments persist over time for both patients and husbands. Northouse (1989) also found, using a descriptive study to assess the

adjustment concerns of patients and husbands after a mastectomy, that survival concerns were the predominant worry reported by patients and husbands in the hospital and at one month post-surgery.

The ABMT treatment raises issues of loss and brings with it fears and death anxiety (Wochna, 1997). Sharing the breast cancer patient's existential concerns regarding death may be anxiety provoking for the PCG. The spouse of a critically ill patient may experience a plethora of feelings and emotions such as anxiety, fear, guilt, depression, anger, and loneliness (Wochna, 1997). Foxall & Gaston-Johansson (1996) in a descriptive study of 24 family caregivers of BMT patients found that caregivers reported more anxiety and depression pre-BMT than on BMT days +5 and +20. Also, objective burden was related significantly to depression and symptom distress on BMT day +5 and to anxiety and symptom distress on BMT day +20.

Fatigue

The numerous responsibilities and responses to the patient's condition inherent in the caregiver role such as chauffeur, confidante, homemaker, child care provider, hypervigilance, and worry may engender fatigue. Caregiver fatigue is significant when the care demands produce situations demanding constant, vigilant care (Andrews & Elfert, 1989; Jessop & Stein, 1985). Foxall and Gaston-Johansson (1996) found that among the most frequently reported areas of objective burden was "not enough energy".

Contributing to the caregiver fatigue may be the shift from the ABMT treatment being totally completed in the inpatient setting to varied portions of the treatment and care being delivered in the ambulatory setting. Patients are being discharged from the hospital when they may still perceive themselves as acutely ill (Laizner, Yost, King, McCorkle, 1993). This shift in treatment location increases dramatically the need for the PCG's transportation role, symptom management skills, crisis intervention skills, and hypervigilant behaviors. This enmeshing of the PCG within the ABMT

process and sequelae may lead to increased fatigue. Caregivers should be screened for fatigue in the pre- ABMT period, with particular attention given to those caregivers who describe themselves as very burdened and exhausted (Foxall, & Gaston-Johansson, 1996).

Burden of Care

Burden of care (BOC) has been explored in caregivers of cancer patients for over three decades. Burden is the caregiver's response to the stressors engendered by caring for the cancer patient. This action may result in a negative perception of caregiving by the caregiver (Bull, 1990). Numerous sources of caregiver burden exist in the ABMT experience: uncertainly of the treatment outcomes; negative sequelae of the treatment or disease; invasive medical procedures; existential considerations regarding mortality; isolation; and disruptions in the work or home environment (Patneaude, 1990; Zabora et al., 1992).

Burden may be conceptualized as a unidimensional (Zarit, Roever, & Bach-Peterson, 1980) or as a multidimensional concept with objective and subjective components (Bull, 1990; Montgomery et al., 1995). Objective burden is defined as concrete events, happenings and activities related to caregiving such as financial problems, and personal activity limitations (Hoenig & Hamilton, 1966, 1969). Subjective burden is defined as affective response to the caregiver experience such as feelings and emotions related to fear, strain, or guilt (Montgomery, Gooyea, & Hooyman, 1985). Emotional strain of caregiving burden has been found to be more burdensome than activities related to providing care or disruptions in everyday family life (Bowers, 1987; Hoenig & Hamilton, 1966). Caregiver burden has been found to be highly predictive of depression in some caregivers (Baillie, et al., 1988; Bull, 1990, Reinhard, 1994) but not in others (Robinson, 1983). Burden and anxiety were found to be significantly correlated by Robinson.

Oberst, Thomas, Gass, & Ward (1989) appraised the intensity of four possible appraisals of

caregiving (harm/loss; threat; challenge; benign) in a study of 47 persons involved in the care of patients receiving ambulatory radiation therapy for cancer using the Appraisal of Caregiving Scale (ACS). Time spent in caregiving activities was assessed using the Caregiver Load Scale. Results showed that most time was spent in providing transportation, giving emotional support, and in doing extra household chores (Oberst et al., 1989). Caregiver load correlated positively with treatment length and with patient dependency. Caregivers in the poorest health, with the least education, and those of lower socioeconomic status scored higher on the ACS appraisals of harm/loss and threat.

Family demands, difficulties, and BOC were explored by Carey, Oberst, McCubbib, and Hughes (1991) in 49 family caregivers of patients receiving chemotherapy in the ambulatory clinic setting. Giving emotional support was found to be the most difficult and time consuming task and burden was predicted by the level of patient dependency in agreement with Oberst et al. (1989). Caregivers' appraisal of their situation may mediate both the effects of illness and contextual factors on caregiver outcomes. Hardiness was found to be an important caregiver quality.

Kurtz, Kurtz, Given, and Given (1995) examined in a sample of 150 cancer patients and caregivers relationships among the patient's physical functioning, depression, and symptomatology, impact on caregivers' schedule and health, and caregiver depression. The disposition of caregiver optimism was a strong predictor of caregiver reactions to the burdens of caring.

There is a paucity of research exploring caregiver burden in the allogeneic and ABMT patient populations. Foxall and Gaston-Johansson (1995) found that with respect to subjective burden, caregivers stated that it was painful to see their relative suffer and that they felt unappreciated pre-BMT. The impact of caregiving on caregivers was explored by Nijboer, Tempelaar, Sanderman et al. (1998). The progress of the cancer led to care tasks which were perceived as either negative (burden) or positive by the caregiver. The caregiver's health was impacted by these negative or positive

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effects.

Quality of Life

Quality of life (QOL) has been conceptualized to include four domains: physical; psychological; social; and functional (McMillian & Mahon, 1994). Loveys and Klaich (1991) reported fourteen demands of illness domains experienced by breast cancer patients, all of which may impact the QOL of the PCG: treatment issues such as direct interaction with members of the health care community; changes in life context/perspective; acceptance of illness; social interaction/support; physical changes; reconstructing the self; uncertainty; making comparisons; acquiring new knowledge; making choices; mortality issues; financial/occupational concerns; and making a contribution. Financial concerns have been mentioned by numerous authors (Blank et al., 1989; Hinds, 1985; Jansen, Hillburton, Dibble, & Dodd, 1993).

The high risk of role disruption occurring when the female breast cancer patient is admitted to the hospital for her ABMT treatment (Wochna, 1997) may affect the QOL of the PCG. The patient's partner must assume increased family care responsibilities when one family member is admitted to the hospital. The balance of increased family responsibilities and career expectations is delicate and may lead to changes in usual stress-reducing social interactions. Symptomatology such as fatigue experienced by the PCG may compound the already challenging increased workload and lead to a decrease in QOL. The perception of the terminal patient's QOL may affect the caregiver's QOL (McMillain & Mahon, 1994).

Methodology

Sample and Setting

This study used a descriptive, correlational and predictive design. A convenience sample of 102 PCGs of women with stage II, stage III, or stage IV breast cancer who had undergone

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mastectomy, completed chemotherapy, and were scheduled for ABMT, were recruited for the study. The time between chemotherapy completion and ABMT varied and no data were collected regarding the length of time between these periods. The setting was an urban National Cancer Institute designated comprehensive cancer center located in the Eastern United States. The study was approved by the Institutional Review Board prior to participant accrual. All participants were recruited by either the physician or the BMT clinical nurse. Written informed consent was obtained from each participant.

The subjects completed the questionnaires in a quiet, comfortable room located in the outpatient clinic. The PCGs were informed that they could take a break at any time during data collection. The BMT clinical nurse specialist provided the baseline questionnaires, answered participants' questions, and retrieved the questionnaires after completion. It took approximately one hour for the subjects to complete the questionnaires.

Instrumentation

A Sociodemographic Form was used to collect demographic and clinical data. The questionnaire included the following information: age, sex, race/ethnicity, marital status, educational level, religion, average yearly household income, occupation and work status.

Fatigue

Fatigue was measured using the Piper Fatigue Scale (PFS)[35] and the Fatigue Visual Analogue Scale (VAS). The PFS was designed to measure fatigue as a multidimensional phenomenon. Therefore, use of the PFS is congruent with the conceptual framework of this study which recognizes that fatigue is a multidimensional symptom.[11] Subjective dimensions of this scale include

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perceptions regarding the temporal, sensory, affective, and severity components of fatigue. Piper (p. 485)[35] stated that in this model of fatigue, "...subjective perception was believed to be key to understanding how fatigue might vary between healthy and ill individuals". The objective dimension includes signs of fatigue which could be validated by physiological, biological, and behavioral means. The scale consists of 41 horizontal VAS items measuring four dimensions of subjective fatigue: a) the temporal dimension (5 items relating to timing, frequency, pattern, and duration of fatigue); b) the intensity/severity dimension (12 items relating to severity, distress, and degrees of disruption in activities of daily living); c) the affective dimension (5 items relating to the emotional meaning of fatigue); and d) the sensory dimension (19 items relating to the physical, emotional, and mental symptoms of fatigue).[35]

Subjects using the PFS are asked to respond to items in terms of how they feel now. Anchors on the VAS vary depending on the item. Individual subscale scores are calculated by measuring each VAS item with a 100mm ruler from the left end to the subject's mark, summing all items within the subscale, then dividing the sum by the number of items on the subscale to obtain a mean value. A total fatigue score is calculated by summing the four scores and dividing by four. In a preliminary study by the PI, Cronbach's alpha estimated for the 4 subscales in ABMT patients ranged from .83 to .98.

Depression

The Beck Depression Inventory (BDI) was used to measure depression in subjects. The BDI consists of 21 items that describe particular symptoms of depression.[37] Subjects respond to a Likert-type scale by rating each item 0 (no symptom) to 3 (severe or persistent presence of the symptom). Scores may range from 0 to 9 (normal), 10 to 15 (mild depression), 16 to 23 (moderate depression),

and 24 to 63 (severe depression). The total possible score (range 0 to 63) is obtained by summing the 21 responses. Reliability and validity have been reported for the BDI.[37]

Burden of Care

Burden of care (BOC) was assessed using the Measurement of Objective Burden (MOB) and the Measurement of Subjective Burden (MSB) scales developed by Montgomery, Gonyea and Hooyman41. The MOB is a 9-item, 5-point scale ranging from (1), " a lot more or better", to (5), "a lot less or worse", designed to assess the extent to which caregiving behaviors have changed the caregiver's lives in nine areas: time for oneself; privacy; money; personal freedom; energy; recreational/social activities; vocational activities; relationships with other family members; and health. The MSB is a 13-item, 5-point scale from (1) "rarely or never" to (5) "most of the time", designed to assess attitudes toward or emotional reactions to the caregiving experience. Items for the MSB were adapted from the 29-item inventory relating to attitudes and feelings about caregiving developed by Zarit and associates[42]. Reported alpha was .85 for the MOB scale and .86 for the MSB scale[41].

Quality of Life

QOL was measured by the Quality of Life Index (QLI), which consisted of 35 items that are categorized into the following subscales[43]: health and functioning, socioeconomic, psychological/ spiritual, and family. The tool uses 6-point ordinal scales to measure both the satisfaction with and the importance placed on each item by the individual. Responses range from 1 (very dissatisfied/unimportant) to 6 (very satisfied/important). Final scores ranged from 0 to 30, with higher scores indicating greater QOL[43].

Data Analysis

Measures of central tendency were used to describe the sample and responses to the instruments. Correlations among multiple dimensions of fatigue and pain, depression and health status were analyzed using Pearson's product moment correlations and Spearman's Rho correlations, as appropriate. Hierarchical multiple linear regression techniques were used to determine the predictors of total health status and perceived health status.

Results

Demographic characteristics of the sample

There were 102 subjects who participated in the study with a mean age of 47.59, standard deviation of 10.76 and scores ranging from 25 to 72. Twenty-four percent of the PCGs were female. Ninety percent were married to the breast cancer patient and 80% had some college education or were college graduates. Nineteen percent of the PCGs did not live with a breast cancer patient. Most PCGs worked full-time, held professional jobs with incomes above $50,000 (Table I).

Table I Here

Symptoms Experienced

Psychological Distress

The PCGs experienced moderate state anxiety at baseline (mean =40.28) that ranged from a low of 22 to high anxiety level of 64. The mean score for trait anxiety was low with a range of 24 to 58 (moderate). The mean depression score was normal (7.83), but the maximum score was 26 which was severe depression for some of the subjects (Table II).

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Table II Here

Fatigue

Mean scores for the different fatigue subscales were low as was the total fatigue score. Of the fatigue subscales, intensity was the lowest (mean = 16.20, range 0 to 71.92). The highest fatigue subscale score was sensory with a mean of 36.04. The greatest maximum fatigue subscale scores were affective (90.60) and temporal (90.50).

Burden of Care and Quality of Life

The burden of care measure was divided into objective and subjective components. The objective burden of care mean score was slightly higher (32.49) than the mean subjective burden (31.27). However the maximum score was lower for the objective burden (42) compared to the subjective burden of care (47).

The mean QOL scores on each of the subscales was low. The highest QOL score was on the family subscale followed by health, spiritual/psychological and lastly, socioeconomic. The range for QOL scores was 0 to a maximum of 24 except for health, which ranged from a minimum of 1.50 to 23.86 (Table II).

Sociodemographic Influences on Study Variables

Married PCGs

There were significantly more male PCGs who were married than female PCGs (Table III). Subjects who were married had significantly more income, and reported less fatigue, and state anxiety than PCGs who were not married. All of the other symptoms and burden of care were less

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severe in married PCGs, although non-significant. Health locus of control and quality of life were also higher in the married group compared to those who were not married.

Table III Here

Differences between female and male PCGs

Significantly more females were single compared to male PCGs. The females were less educated, and had lower incomes than the males. The females reported significantly more state and trait anxiety than the males. Although not significant, the women experienced more depression than the men ($p<.05$) (Table IV).

Table IV Here

Correlations Among Variables

Correlations among demographic, psychological distress (anxiety, depression), fatigue, burden of care and QOL are presented in Table V. Significant correlations were found among study variables and demographic characteristics of the sample. Age was significantly correlated with subjective burden of care ($r = -.265$, $p<.01$); income with the fatigue subscale temporal ($r = -.224$, $p<.05$); state anxiety ($r = -.201$, $p<.05$); and trait anxiety ($r = -.252$, $p<.01$).

All variables were significantly correlated to each other except for subjective burden and temporal and sensory fatigue. The highest correlation for subjective burden of care was with total quality of life ($r = -.469$ $p<0.01$) and objective burden ($r = -.399$) (Table V). The highest correlation for subjective burden was the family subscale of QOL ($r = -.408$, $p<.01$) and total QOL ($-.399$, $p<.01$).

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<u>Predictors of Objective and Subjective Burden of Care</u>

Family, a subscale of QOL was a significant predictor of objective burden of care (t= 2.19, p<.o5). There were no other significant predictors of objective burden among the variables of interest. Age (t= 2.20, p<.05) and trait anxiety (t= 2.02, p<.05) were, however, significant predictors of subjective burden of care.

Discussion

Primary caregivers of patients who are diagnosed with breast cancer and treated with mastectomy and scheduled for ABMT, experienced a low-grade fatigue, moderate anxiety and a high burden of care. Depression does not appear to be a problem during the pre-hospitalization ABMT period, which is the period before the patient receives high dose chemotherapy in preparation for the ABMT. Quality of life for all the subscales (health, socioeconomic, spiritual/psychological and family) were below 10 which can be seen as troublesome since the highest possible score is 30. In addition, both objective and subjective burden of care are of concern. This is especially true for single female PCGs. All symptoms were more severe in females compared to males. Nine percent of the sample was either single or widowed and lived alone. This may mean that these PCGs are trying to accommodate the patients needs and still meet their own needs of having a separate household.

Health care providers need to include in their plan of care, ways of helping PCGs deal with psychological distress, and quality of life issue. When resources are limited, the results of this study may be useful in identifying PCGs who are more in need of immediate help.

A key health care provider behavior that reduces psychological distress, as viewed by the

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family with cancer, is the provision of accurate information in a timely fashion (Hilton, 1993 Kristjanson & Ashcroft, 1994, Tringali, 1986). Information seeking is considered to be a general coping strategy (Weisman, 1979) to decrease anxiety and increase a sense of control (Tringali, 1986). Difficulty inherent in family members acquiring information regarding treatment or patient status has been documented frequently in the literature (Stetz, McDonald, Compton, 1996; Wright & Dyck, 1984). Health care professionals can enhance caring relationships with caregivers through acknowledging caregivers as individuals and providing clear expectations of the family caregiver role (Compton, McDonald, & Stetz, 1996).

An additional concern for PCGs of breast cancer ABMT patients is the rapid shift of ABMT cancer treatment from the inpatient to the ambulatory care setting and home care environment during the past decade. This will dramatically affected the role of the PCG, given the fact that our findings showed that prior to the ABMT, the PCG suffered from a high burden of care and a low quality of life. This role expansion has impacted and often increased the psychological distress, fatigue, and burden of care, while decreasing the quality of life of the PCG.

Needs of Primary Caregivers

Numerous researchers have explored specific needs of the PCGs of cancer patients functioning in diverse settings. Tringali (1986) ranked caregiver needs of cancer patients who had received either radiation therapy or chemotherapy with the most important as having their questions answered honestly concerning the patient's disease, treatment and prognosis, need for hope, and need to trust the staff's expertise and their concern for the patient as a person. Thorne (1985) stated that caregivers felt a tremendous need to live as normally as possible, have faith in medical professionals, and maintain a positive attitude.

The findings from this study have added to the ever growing list of the needs of PCGs of

cancer patients who receive care in an outpatient setting. Wingate and Lackey (1989) described the needs of the caregivers of noninstitutionalized cancer patients as psychological, household management, information, respite, legal/financial, spiritual, physical and other. Blank, Clark, Longman, and Atwood (1989) stated perceived home care needs of caregivers of cancer patients receiving ambulatory treatment for cancer as treatment uncertainty, physical restriction/role change, anger/depression, isolation, lack of support, transportation, and finances. The spouse's needs regarding caring for a terminally ill adult patient at home were explored by Stetz (1987). Caregiving demands included managing the physical care, treatment regimen and the imposed changes, managing the household and finances, standing by, alterations in caregiver well-being and patterns of living, constant vigilance, unmet expectations from the health care system, cancer itself, anticipating the future, and alteration in relationship to ill spouse. Caregivers of home-based cancer patients receiving outpatient radiation therapy and/or biological response modifiers stated very important needs as being assured that the patient is comfortable, involvement with health care and health care providers, and being kept apprised of any changes (Longman, Atwood, Sherman, Benedict, & Shang, 1991). Caregivers of home hospice cancer patients needed time for themselves to attend to their personal needs, lacked sufficient time to rest, and did not experience adequate sleep (Steele & Fitch, 1996). Caregivers of both clinic and hospice cancer patients ranked information and spiritual needs as most important (Harrington, Lackey, & Gates, 1996).

Implications for Nursing Practice

Oncology nurses practice in fast paced clinical environments in which the timing of clinical and supportive care is often guided by critical pathways. Therefore it is imperative for the nurse-patient-PCG interaction to be appropriate, adequate, effective, and efficient. Nursing interventions

need to be tailored to the needs of the PCG and delivered proactively. Results of previous research should be used to provide anticipatory guidance to the PCG functioning within the family cancer experience. Waiting for the PCG to request information before any interventions are offered may lead to the PCG exceeding his/her coping strategies and experiencing synergistic distresses. Therefore, the proactive use of research-driven interventions to decrease negative sequelae of the PCG's perception of the ABMT experience is critical.

Implications for Future Research

A dramatic increase in the population of minority and elderly patients with cancer is predicted for the next decade (Boyle, 1994). The research conducted previously with ABMT breast cancer patients, as well as other patient populations has primarily used small, single site, select samples similar to this study. These high income, primarily Caucasian samples, while representative of the United States ABMT population, do not yield information regarding outcomes of patients from diverse cultures, ethnicities, and socioeconomic statuses. Investigation of economic, cultural and related barriers for breast cancer patients to receive ABMT is a research priority. If these barriers are not identified and the results not used to increase the inclusion of diverse minority and socioeconomic populations in the ABMT treatment process, the populations from which nurse researchers sample will remain the same and extrapolation of findings will be hindered.

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Table I: Demographic Characteristics of Primary Care Givers (Frequency)

Characteristics	n	%
Gender		
Female	25	24.51
Male	77	75.49
Race		
White	89	87.25
African American	9	8.82
Hispanic	1	.98
Asian	2	1.96
Other	1	.98
Marital status		
Married	92	90.20
Single	9	8.82
Widowed	1	.98
Education completed		
Grade School	2	1.96
High School	19	18.63
Some College	26	25.49
College Graduate	36	35.29
Graduate Degree	19	18.63
Religion		
Catholic	23	22.55
Protestant	47	46.08
Jewish	5	4.90
Other	16	15.69
None	9	8.82
Missing	2	1.96
Patient lives with		
Spouse	89	87.25
Significant other	3	2.94
Child	0	0.00
Parent	0	0.00
Self	9	8.82
Missing	1	.98

Average yearly income		
less than $20K	4	3.92
$20-29K	8	7.84
$30-39K	5	4.90
$40-49K	15	14.71
more than $50K	65	63.73
Missing	5	4.90
Occupation		
Professional	62	60.78
Technical	13	12.75
Retired	12	11.76
Other	15	14.71
Missing	0	0.00
Work status		
Full-time	78	76.47
Part-time	7	6.86
Unemployed-resigned	5	4.90
Unemployed –Disability	2	1.96
Unemployed –Retired	8	7.84
Missing	2	1.96

Table II: Means, standard deviations, and ranges of study variables

	Mean	STD	Minimum	Maximum
Fatigue				
Intensity	16.20	16.83	0.00	71.92
Temporal	31.43	21.13	0.00	90.50
Affective	32.00	24.73	0.00	90.60
Sensory	36.04	20.72	0.00	76.58
Total	28.52	18.46	0.00	75.38
Depression	7.83	5.69	0.00	26.00
State Anxiety	40.28	10.92	22.00	64.00
Trait Anxiety	37.40	7.91	24.00	58.00
	8.75	6.29	0.00	28.57
QOL				
Socioeconomic	8.83	6.26	0.00	29.44
Spiritual/Psychological	8.75	6.35	0.00	30.00
Family	8.08	7.08	-2.50	30.00
Objective Burden	32.12	9.05	-48.60	43.00
Subjective Burden	32.17	32.31	15.00	351.00

Table III: Comparison of selected variables by marital status

	Married			Other			t-value	df	p-value
	Mean	Valid N	STD	Mean	Valid N	STD			
Demographics									
Age	48.21	92	10.19	41.90	10	14.43	1.780	100	.078
Sex	1.80	92	.40	1.30	10	.48	3.720	100	.000
Race	1.11	92	.31	1.30	10	.48	-1.731	100	.086
Education	3.55	92	1.03	3.00	10	1.25	1.582	100	.117
Income	4.49	88	.97	2.78	9	1.64	4.683	95	.000
Work	1.34	90	.71	1.60	10	.97	-1.045	98	.298
Intensive	15.85	92	16.75	19.41	10	18.15	-.634	100	.528
Temporal	30.40	92	20.93	40.86	10	21.68	-1.495	100	.138
Affective	30.82	87	25.52	42.24	10	13.11	-1.389	95	.168
Sensory	34.47	91	20.75	50.34	10	14.48	-2.351	99	.021
Total	27.46	92	18.60	38.21	10	14.57	-1.766	100	.080
Depression	7.23	92	5.50	10.22	10	4.86	-1.644	100	.103
Anxiety									
State	39.35	91	10.65	48.77	10	10.04	-2.668	99	.009
Trait	36.94	91	7.84	41.60	10	7.71	-1.787	99	.077
QOL									
Health	6.74	91	6.22	8.77	10	7.16	-.012	99	.991
Socioeconomic	8.86	91	6.20	8.78	10	6.92	.047	99	.962
Spirit/Psycho	8.77	91	6.27	8.71	10	7.28	.026	99	.960
Family	8.18	91	6.90	7.01	9	7.21	.481	98	.631
Burden of Care									
Objective	32.69	92	3.96	30.63	10	3.23	1.591	100	.115
Subjective	30.95	91	5.24	34.13	10	6.66	-1.768	99	.080

Table IV: Comparison of selected variables between female and male caregivers

	Female			Male			t-value	df	p-value
	Mean	Valid N	STD	Mean	Valid N	STD			
Demographics									
Age	49.56	25	14.04	46.95	77	9.48	1.056	100	.294
Sex	1.20	25	.41	1.10	77	.31	1.249	100	.214
Race	1.28	25	.46	1.04	77	.19	3.720	100	.000
Education	2.80	25	1.00	3.73	77	.98	-4.084	100	.000
Income	3.67	24	1.55	4.55	73	.90	-3.428	95	.001
Work	1.96	24	.95	1.18	76	.53	5.028	98	.000
Intensive	19.94	25	17.66	14.98	77	16.49	1.28	100	.202
Temporal	36.14	25	19.17	29.90	77	21.62	1.29	100	.201
Affective	32.40	25	19.57	31.86	72	26.41	.09	95	.925
Sensory	39.03	25	20.76	35.06	76	20.74	.83	99	.408
Total	31.88	25	16.61	27.43	77	19.00	1.05	100	.298
Depression	9.32	25	5.43	6.94	77	5.42	1.90	100	.060
Anxiety									
State	44.28	25	11.31	38.96	76	10.53	2.15	99	.034
Trait	41.25	25	6.92	36.13	76	7.85	2.91	99	.005
QOL									
Health	9.51	25	7.08	8.49	76	6.03	.70	99	.486
Socioeconomic	9.55	25	6.87	8.62	76	6.05	.64	99	.521
Spirit/Psych	9.38	25	7.17	8.56	76	6.08	.55	99	.580
Family	8.77	24	7.62	7.86	76	6.69	.56	98	.576
Burden of Care									
Objective	32.33	25	4.42	32.54	77	3.78	-.23	100	.819
Subjective	30.68	25	5.65	31.46	76	5.39	-.62	99	.534

Table V: Correlations Between Fatigue, Quality of Life, and Selected Variables, using Pearson's Correlation

	Fatigue Total	Temporal	Affective	Sensory	Intensity	QLI Total	Family	Health	Spiritual	Socioec	Depression	BOC Subjective	BOC Objective	Anxiety State	Trait
Fatigue Total	1														
Temporal	.844**	1													
Affective	.892**	.603**	1												
Sensory	.893**	.648**	.753**	1											
Intensity	.876**	.697**	.702**	.723**	1										
QLI Total	-.547**	-.413**	-.477**	-.547**	-.478**	1									
Family	-.351**	-.203*	-.400	-.339**	-.284**	.744**	1								
Health	-.550**	-.455**	-.439**	-.519**	-.514**	.868**	-.450**	1							
Spiritual	-.500**	-.396**	-.398**	-.527**	-.132**	.870**	.474**	.752**	1						
Socio.	-.430**	-.341**	-.334**	-.446**	-.384**	.840**	.424**	.737**	.694**	1					
Depression	.673**	.576**	.492**	.639**	.660**	-.582**	-.257**	-.613**	-.595**	-.510**	1				
BOC Subjective	.254**	.197*	.258**	.248**	.182	-.418**	-.388**	-.339**	-.330**	-.334**	.263**	1			
Objective	.314**	.235*	.259**	.319**	.272**	-.469**	-.397**	-.462**	-.376**	-.319**	.342**	.292**	1		
Anxiety State	.541**	.324**	.492**	.603**	.491**	-.558**	-.380**	-.492**	-.506**	-.484**	.664**	.333**	.346**	1	
Trait	.500**	.405**	.383**	.456**	.546**	-.649**	-.410**	-.611**	-.621**	-.532**	.641**	.403**	.407**	.669**	1

* significant at the .05 level
** significant at the .01 level

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Appendix 9

The Effects of a Comprehensive Coping Strategy Program on QOL and Mortality (Abstract)

ABSTRACT FORM

Title: The Effects of a Comprehensive Coping Strategy Program on Mortality and Quality of Life (QOL)

Authors: Fannie Gaston-Johansson, DrMedSc, RN, FAAN

City, Country: Baltimore, USA

Background: Patients with breast cancer who undergo autologous bone marrow transplant (ABMT) experience multiple symptoms such as pain, psychological distress, nausea and fatigue which have an adverse effect on their quality of life. These symptoms are not entirely eliminated by traditional treatment strategies. The purpose of this study was to determine if a Comprehensive Coping Strategy Program (CCSP) had an effect on specific symptoms, mortality and QOL in breast cancer patients treated with autotransplantation (AT).

Methods: The sample size was 73 with 38 patients randomized to the CCSP. A RCCT was used to compare QOL between the experimental CCSP group and the control group who received usual care. The CCSP was taught to patients at least two weeks prior to admission to hospital, pre-treatment, and reinforced periodically post-treatment during hospitalization. Data were collected at baseline and 1½ years later using standardized questionnaires.

Results: The CCSP group reported significantly less nausea ($p<0.05$) and nausea combined with fatigue ($p<.05$) than the control group following the ABMT. Pain, depression and fatigue accounts for over 50% of the variance in health status of these patients. Subjects receiving the CCSP were 9% less likely to die ($p<0.05$) than those in the control group. The CCSP subjects also reported significantly better overall QOL ($p<0.01$), physical functioning ($p<0.05$). Hierarchical ANCOVA models measuring the effectiveness of CCSP on QOL as follow-up and tested with incremental adjustment factors showed that the CCSP significantly improved overall QOL ($p<0.05$), physical functioning ($p<0.05$) and psychological/spiritual aspects QOL ($p<0.01$).